California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA

Enforcement Committee
Note: There will be no WorkGroup on E-Pedigree Meeting until 2009

Contact Person: Virginia Herold
(916) 574-7911

Date: December 9, 2008
Time: 9:30 a.m. – 1:00 p.m.
Place: Department of Consumer Affairs
Hearing Room, Suite S-102
1625 N. Market Boulevard
Sacramento, CA 95834

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Leech at (916) 574-7912, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend but may not vote.

MEETING AGENDA
Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

1. Call to Order   9:30 a.m.

1. Update on the Implementation of Drug Take Back Programs from Patients (SB 966, Simitian, Chapter 542, Statutes of 2007)
2. Discussion of Sharps Take Back by Pharmacies
3. E-Prescribing Discussion
4. Fingerprinting Initiative of the Department of Consumer Affairs for Health-Related Boards
5. Citation and Fine Program Overview 2007-2008
6. DEA Policy on Correcting Schedule II Prescriptions
7. Theft of Dangerous Drugs from the Pharmaceutical Supply Chain
8. Public Comment for Items Not on the Agenda*

    (Note: the committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))

Adjournment   1:00 p.m.

Note: Adjournment time is approximate

Meeting materials will be available from the board's Web site by December 2, 2008

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: December 2, 2008

To: Enforcement Committee

Subject: Update on Take-Back Drug Programs in Pharmacies

Background:
Last year, SB 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated Waste Management Board to develop the parameters for "model" drug take-back programs in pharmacies (a copy of this law follows). These model programs are intended to provide consumers with the ability to dispose of unwanted prescription and OTC drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage. Under SB 966, these guidelines must be in place by December 2008.

State and federal law regulates prescription medicine until it is dispensed to patients. It is not regulated again unless it is collected at consolidated points, at which point it becomes medical waste, and must be handled and destroyed in specific, mandated ways.

Patients are often confounded about what to do with unwanted medicine. Californians are increasingly wanting "green" options for disposing of unwanted medicine, which current law does not allow. There is no viable process, other than to make the discarded drug products unpalatable (mixing with kitty litter or other substance, wrapping in duct tape, etc.) and then placing them in the trash. Some drugs may be flushed down the toilet, and are specifically labeled by the manufacturer to dispose of in this manner.

Pharmacies have in some cases agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not authorized in law.

Some communities periodically offer community take-back events, or special days at landfills where the public can take back drugs.

Some drug manufacturers (and the state of Maine, where there is a pilot program underway) provide mailers that patients can use to send unwanted medicine to a predetermined location for destruction. This is the process preferred by the DEA for controlled drugs.

The greatest problem for the board with drug take-back programs is the potential for these drugs to be diverted to the streets. There is a serious prescription drug abuse problem in the US, and the uncontrolled aggregation of prescription medicine is an

attractive enticement. In some cases, drugs collected in collection bins could re-enter the prescription drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain.

Pharmacies are areas where health care is provided – concern has been expressed that it is difficult for this purpose to be combined with a recycling center, where high sanitation is not necessarily a priority.

Pharmacies also have expressed concern that they may be required to absorb the costs of paying for disposal of these returned drugs, for sorting out controlled drugs (which potentially would require a pharmacist's time) and for assuring the safety and periodic emptying of collection bins.

Update for this meeting:
At the October 2008 Board Meeting, the board discussed concern with the initial proposed model program guidelines as drafted by the Integrated Waste Management Board. However, the board did express its support for such programs on a voluntary basis.

Immediately before the October Board Meeting, the Integrated Waste Management Board issued new guidelines, incorporating some of the changes suggested by the staff. The board then directed Executive Officer Herold to provide the board's concerns with provisions in the draft model program guidelines at a committee meeting of the Integrated Waste Management Board (CIWMB) on November 10.

Ms. Herold provided this testimony and submitted written comments (attached letter following this memorandum).

On November 13, the CIMWB adopted the Model Guidelines (attached), without incorporating the additional changes listed in the board's November letter. However, a number of other entities also provided comments to guidelines. For this reason, the CIMWB agreed to consider modifications to the Model Guidelines, perhaps at its February 2009 meeting. Proposed comments on the adopted guidelines that have been submitted to the CIMWB will be evaluated during a public meeting on December 19.

The Enforcement Committee needs to discuss whether additional concerns (besides those listed in the attached letter) exist.

Additionally, Senator Simitian has introduced SB 26, which would direct the board to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop sustainable efficient policies to manage pharmaceutical wastes and the disposal of devices. A copy of this bill, which the board will discuss at its January meeting, is also included in this tab section.
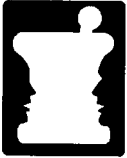
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: California Integrated Waste Management Board

Date: November 10, 2008

Subject: Model Home-Generated Pharmaceutical Waste Comments

The California State Board of Pharmacy regulates those who ship, store, transport, sell and dispense prescription drugs to patients and practitioners in California, and ship prescription drugs and devices into from and throughout CA. We license approximately 6,600 pharmacies in California, 500 of which are hospital pharmacies. We license nearly 110,000 individuals and other businesses involved with prescription drug distribution.

Prescription drugs are tightly regulated down to the consumer level – the manufacturer is licensed, the wholesalers are licensed, the pharmacies are licensed, the practitioners who prescribe and sometimes dispense are licensed. However, once drugs are dispensed to the patient, there are no legal ways for the patient to destroy unwanted/unneeded drugs. Consumers often either toss them into the trash, or flush them down the toilet.

Prescription drugs are not regulated again unless they are aggregated. When they become pharmaceutical or medical waste, and then once again, only licensed entities can handle this waste.

This regulation is important for a number of reasons. Foremost is to preserve the quality of our prescription medicine supply and the health of the public. Diversion of prescription drugs and prescription drug abuse are two societal issues exist, that make aggregation of unused prescription drugs valuable and attractive to criminals.
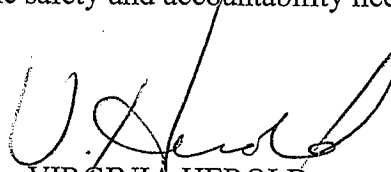
For the last six months, Board of Pharmacy staff has worked with a small working group of other state agencies, including the CIWMB, on the model programs. Recently, we provided comments on the proposed model program guidelines, and many of our recommendations have been incorporated into the draft before the committee.

At this time, on behalf of the Board of Pharmacy, I wish to make the following statements:
1. California needs to develop a system to aid the public in disposing of their pharmaceuticals in an appropriate, environmentally safe manner.
2. The Board of Pharmacy believes that only the following entities should be authorized to operate take-back programs:
    - California-licensed pharmacies with active, unrestricted licensed from the Board of Pharmacy
    - Government agencies (local, county, state, federal)
    - Police or sheriff's offices

- Licensed medication practitioners who are authorized to prescribe in California under Business and Professions Code section 4170(c), with active, unrestricted licenses.
- Hazardous waste collection sites

3. The greatest weakness in the model program guidelines are that they are not in regulation form. As such, enforcement of these provisions will be difficult for the regulatory agencies involved. The Board of Pharmacy is likely to correct this via legislation and regulations in 2009. Consequently, the model guidelines will provide entities operating take back programs with direction with respect to operating these programs, but enforcement provisions (currently identified on page 4-3 as new item G) needs augmentation and development.

4. The board is greatly concerned with diversion of prescription drugs from these sites (whether in pharmacies themselves or in community events) into pharmacies, where they will be re-dispensed to patients. Recently in Washington State, which has allowed pharmacies under a pilot program take back drugs, a pharmacist was arrested who took back drugs, placed them into the current inventory of the pharmacy and then dispensed them to patients. (Attachment 1 to this document.) The risks of prescription drugs being diverted by pharmacies operating such programs, or purchasing drugs from others in the community who operate such take-back programs, are a real concern and threat to our drug supply.

5. We have concern the assertion that cost-effective collection is possible at pharmacies, if the pharmacy cannot charge for the collection costs (page 4-3, item A).

6. The drugs should not be reviewed by staff at the collection site before being deposited into the collection device. When patients handle the drugs and deposit the drugs themselves, there should be no reason for labeling describing what the medicine is "in the event of poisoning" (page 4-5, lower list, item 4).

7. Printed advertisements for community take back events should list who is responsible for operation of the collection location, including the name, address, and phone number of the responsible party.

8. Every operator of a model program must have written policies and procedures to document their operations and compliance with the guidelines.

9. Thefts or suspected thefts from any collection site need to be reported within 24 hours at least to the police, the Board of Pharmacy and the CDPH.

10. On one-day events—we strongly recommend that the pharmaceutical waste must be picked up at the end of the day. It cannot be temporarily stored anywhere, even if the signs on the bins are removed (Pages 4 -3 and 4-14).

11. There needs correction of an inconsistency: a pharmacy may assist at one-day events (page 4-12) but must assist later in this section (page 4- 17).

Thank you. We look forward to continuing to work on developing these programs so that they provide the public with the options they seek, and the safety and accountability needed to protect our prescription drug supply.

VIRGINIA HEROLD
Executive Officer

News Release
FOR IMMEDIATE RELEASE
November 04, 2008
Contact: Jodie Underwood
Number: (206) 553-1162

Edmonds Pharmacy "Manager of the Year" Pleads Guilty
Thousands of Pills Involved, Including Oxycodone and Hydrocodone

NOV 04 -- (Seattle) – DEA Special Agent in Charge (SAC) Arnold R. Moorin and the United States Attorney for the Western District of Washington, Jeffrey Sullivan, announced that on October 31, 2008, Milton W. Cheung, a Washington State licensed pharmacist, entered guilty pleas to two felony offenses: Acquiring Controlled Substances by Deception and Misbranding Drugs. These offenses are punishable by up to four years in prison, a $250,000 fine, and up to one year of supervised release. Cheung is set for sentencing on February 13, 2009.

Cheung, 55, of Lynnwood, Washington, has been employed for the last several years as a Pharmacy Manager at the Top Food Drug Store, in Edmonds, Washington. As pharmacy manager, Cheung was the principal pharmacist responsible for the daily activities and operations at the Edmonds Top Food Drug Store. From 2003 continuing through September 2008 (when he resigned), Cheung was named Pharmacy Manager of the Year, by Haggen Incorporated, the owner of Top Food Drug Store.

During 2007, and continuing through September 2008, Cheung solicited a number of Washington State medical providers, including doctors, hospices, and clinics, as well as Top Food Drug Store customers, to provide expired and unexpired drugs to him at the Edmonds Top Food Drug Store, on the alleged basis that he would provide these drugs to less developed countries as part of a philanthropic mission. While Cheung collected these drugs, he purposefully diverted much of the drugs collected by placing the drugs into the regular supply bottles at the Top Food Drug Store. This gave him a much larger inventory of drugs to distribute to pharmacy customers and made the pharmacy which he managed appear more profitable. Cheung then proceeded to distribute these returned drugs to customers at the Edmonds Top Food Drug Store when filling new customer prescriptions, even though a large portion of these drugs were expired, and despite the fact that all of the drugs had been adulterated in that they had already been distributed to and possessed by others, and were returned merchandise which Cheung was doling out as new inventory. Among the drugs deceptively collected by Cheung and later distributed by him, were such Schedule II through IV controlled substances as fentanyl, methadone, morphine, oxycodone, hydrocodone, and lorazapam, in addition to other drugs.

All prescription drugs carry an expiration date after which the drugs are no longer regarded as medically effective or safe to consumers. The entire drug re-distribution scheme conducted by Cheung, under the guise of providing drugs to developing nations, was unlawful; no such program had been sanctioned by the DEA or any other valid regulatory authority. In addition, all prescription medications in pharmacies are required by federal regulation to be maintained in stock containers which show their true lot number and expiration date. This is done to ensure the safety of what is being sold and distributed to the public. Cheung's prescription misbranding effectively countermanded and negated these safeguards.

In September 2008, in response to the criminal conduct by Cheung, Haggen Incorporated issued a drug recall, printed in the Seattle Times, advising customers of the Edmonds Top Food Drug Store to return all potentially expired drugs.

This case was investigated by the Drug Enforcement Administration, Internal Revenue Service and the Edmonds Police Department.

CALIFORNIA INTEGRATED WASTE MANAGEMENT BOARD

Resolution 2008-181

Consideration Of Model Programs And Procedures For The Collection And Proper Disposal Of Pharmaceutical Waste As Required By Public Resources Code Section 47102 Et. Seq. And Discussion Of Management Of Sharps

WHEREAS, Public Resources Code (PRC) Section 47122 (a) (1) requires the California Integrated Waste Management Board (Board) in consultation with appropriate state, local, and federal agencies, including, but not limited to, the Department of Toxic Substances Control, California Department of Public Health, the State Water Resources Control Board, and the California State Board of Pharmacy, to develop model programs for the collection and proper disposal of pharmaceutical waste; and

WHEREAS, PRC Section 47122 (a) (1) requires the Board to establish for participants, criteria and procedures for the implementation of the model programs for the collection and proper disposal of pharmaceutical waste; and

WHEREAS, PRC Section 47122 (a) (2) requires the Board to evaluate a variety of models used by other state, local, and other governmental entities, and to consider a variety of potential participants that may be appropriate for the collection and disposal of pharmaceutical waste; and

WHEREAS, PRC Section 47122 (3) requires the Board to make the model programs available to eligible participants no sooner than July 1, 2008, but no later than December 1, 2008; and

WHEREAS, PRC Section 47123 requires the Board to report to the Legislature no later than December 1, 2010 on the efficacy, safety, statewide accessibility, and cost effectiveness of the model programs; and

WHEREAS, the Board held two workshops and conducted a survey of other state and international programs with regard to collection and proper disposal of pharmaceutical waste; and

WHEREAS, results of the aforementioned survey were tabulated and best management practices for collection and proper disposal of pharmaceutical waste were developed in conjunction with the Department of Toxic Substances Control, California Department of Public Health, the State Water Resources Control Board and the California State Board of Pharmacy.

(over)

NOW, THEREFORE, BE IT RESOLVED the Board approves the Criteria and Procedures for Model Pharmaceutical Waste Collection and Disposal Programs.

CERTIFICATION

The undersigned Executive Director, or his designee, of the California Integrated Waste Management Board does hereby certify that the foregoing is a full, true, and correct copy of a resolution duly and regularly adopted at a meeting of the California Integrated Waste Management Board held on November 13, 2008.

Dated:

Mark Leary
Executive Director

Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB) to develop model programs for the collection from consumers and proper disposal of unused or expired home-generated pharmaceuticals[1]. In developing model programs in California, the CIWMB is also required to evaluate programs used by other state, local, and other governmental entities. The CIWMB provided a survey to those entities that have collection programs and requested that they complete and return it to the CIWMB. The purpose of the survey was to acquire information on existing home-generated pharmaceutical waste collection programs in California. From the survey results, the Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs (Procedures) were developed that would help organizations or local governments create programs through which the public may return unused or expired home-generated pharmaceutical waste (typically a prescription drug dispensed to a consumer, or a non-prescription item, such as over the counter drugs, that are no longer wanted or needed by the consumer) and meet the following minimum criteria and goals of SB 966 and of the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health (CDPH), Board of Pharmacy, Department of Toxic Substances Control, and the State Water Resources Control Board).

The minimum criteria of SB 966 and of the Pharmaceutical Working Group for home-generated pharmaceutical waste collection programs are as follows:

1. Requires, at no additional cost to the consumer, the safe and environmentally sound take back and disposal of unused or expired home-generated pharmaceuticals;
2. Ensures protection of the public's health and safety and the environment;
3. Ensures protection of the health and safety of consumers, and employees;
4. Report to the Board the amounts of home-generated pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability, and incidents of diversion of drugs for use or sale;
5. Protects against the potential for the diversion of drug waste for unlawful use or sale;
6. Provides notices and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
7. Subjects persons or businesses to consequences for failure to comply with model programs per SB 966 and related state and federal pharmaceutical and waste management statutes at the point of transportation, deposition, and consolidation;

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1 Throughout this document, the terms "home-generated pharmaceuticals" or "home-generated pharmaceutical waste" are used. Although the term does not appear in the law establishing this program, it is the term commonly used by stakeholders to refer to unused or expired pharmaceuticals in the possession of consumers.

8. Requires that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste must be managed as medical or hazardous waste. This would include all statutory requirements for storage and handling as medical or hazardous waste, the use of registered medical or hazardous waste haulers and approved treatment technology for disposal; and

9. Requires collection locations to have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.

Additional goals of SB 966 and the Pharmaceutical Working Group include:

1. Provides for the collection of home-generated pharmaceuticals that is convenient for consumers

2. Maintains privacy of all participants;

3. Prevents the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;

4. Ensures that medication information is legible, so that it can be identified in case of a poisoning;

5. Develops a sustainable funding source for collection and disposal of home-generated pharmaceuticals, such as grants, utility funding, or advanced disposal fees placed on home-generated pharmaceuticals and local general funds or via extended producer responsibility funding framework.

6. Strives to develop permanent collection programs rather than one-day events, so they will be more accessible to the public; and

7. Provides recommendations for implementation of a statewide program; and

8. Recommends statutory changes to, for example, the Medical Waste Management Act.

The following Procedures have been extracted from both the Pharmaceutical Collection Programs Survey collection program information on the internet, and from the Pharmaceutical Working Group and are required for pharmaceutical collection programs. The Procedures are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used as a model to develop a collection and disposal program for unused/expired home-generated pharmaceuticals. The Procedures are broken down by (I) Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

I. Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs

As mentioned in the previous section on goals, it is preferable that permanent home-generated pharmaceutical collection programs be developed to provide the public with consistently accessible and convenient venues to drop off unused or expired home-generated pharmaceuticals. The following procedures are basic steps that shall be taken to implement permanent collection programs at these types of facilities.

1. **Types of Collection Facilities** – Only the following may maintain permanent collection locations for home-generated pharmaceuticals: pharmacies with active unrestricted licenses from the California State Board of

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Pharmacy, police and sheriff's stations, public/environmental health agencies, physician and other licensed health care prescribers' offices, Household Hazardous Waste (HHW) facilities, and healthcare collection sites. Healthcare collection sites are physical locations licensed or operated by individuals or entities licensed by an agency within the Department of Consumer Affairs (DCA), with these locations electing to collect or take-back home-generated pharmaceutical waste and/or sharps, as applicable. Examples of healthcare collection sites include but are not limited to physicians and surgeons' offices, dentists, veterinary offices and pharmacies. If a DCA licensee has their license revoked, suspended, placed on probation or otherwise limited in any way, it shall not operate a healthcare collection site. If collection is at a police station, law enforcement must agree to and be able to collect the controlled substances and other home-generated pharmaceutical waste. Participation by any entity is voluntary and must be done in accordance with these provisions in these procedures in order to be considered a model program. Jurisdictions such as the City of Los Angeles, San Mateo County, Ventura County, Santa Cruz County, Marin County, Santa Clara County, and nonprofit groups such as the Teleosis Institute are current examples of entities implementing permanent and ongoing programs utilizing these types of venues.

A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB by the governmental entity, organization, or business that is implementing these programs. The list of collection facilities shall include the name, address, contact, and telephone number of the facility collecting and disposing of the home-generated pharmaceutical waste.

2. **Government Agency Authorization** – Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.

3. **Medical/Hazardous Waste Hauler/Disposal Arrangements** - Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at http:www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste

transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. What Can and Cannot Be Collected

a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.

b. Sharps in approved containers may be accepted at collection sites, but shall not be placed in the same containers as the home-generated pharmaceutical waste.

c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall <u>not</u> be accepted.

d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.

5. Signage – Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.), as well as the hours during which collection is permitted. Home-generated pharmaceutical wastes shall be segregated for storage and when placed in a container or secondary container, that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility) which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to the container location. During periods of non-operation this sign shall be removed and the container shall be stored in a secure intermediate storage area.

Signage should also show how to deposit pharmaceuticals into the secured container, since staff cannot assist the consumers. The signage should also advise consumers to remove personal information from the medicine

containers. In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer to participate in a take back program.

6. How Home-Generated Pharmaceuticals Shall Be Collected - If home-generated pharmaceuticals are kept in the original, labeled container, personal information shall be removed or marked out. The containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site are not to assist consumers in placing home-generated pharmaceuticals in the bins. This is the obligation of the consumer. The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

  a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances – If Home-generated pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they shall be emptied from their containers by the consumer into the secured bin/container. Collection site staff may assist a consumer in opening a container but shall not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

  b. Storage – A collection site shall not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated pharmaceutical waste shall not be placed or commingled with expired, recalled or other quarantined drugs in the possession of a collection site. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

  c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in approved containers, cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in approved container and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.

d. <u>Chain of Custody</u>- When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the owner of the pharmaceutical waste and is responsible for assuring that it is stored, transported, and disposed of in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and hauler number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. Staffing - The following staff are recommended at collection programs to implement the specified tasks:

a. <u>Pharmacist (at pharmacies)</u> – The pharmacist may or may not be able to assist any consumer who brings in home-generated pharmaceutical waste or review each consumer's deposit into the collection bin. No pharmacist or pharmacy staff shall accept home-generated pharmaceutical waste directly from consumers. The consumer shall deposit the items into the secured locked container. A pharmacist, if he or she chooses, to assist consumers with the identification of drugs that are unidentified, shall treat those drugs as controlled substances and consumers shall be referred to an appropriate collection location for those items. Alternatively, signage could be displayed stating that the pharmacy will not accept controlled substances for collection and disposal. Additional items that shall not be accepted into the pharmaceutical collection containers include sharps, medical waste and other items identified in the definition section of these procedures.

b. <u>Law Enforcement</u> –If a permanent home-generated pharmaceutical waste collection program decides to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances.

c. <u>Hazardous Waste Company Personnel (for collection at HHW facilities)</u> - Hazardous waste personnel will provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork,

transport non-controlled substances for hazardous waste destruction, remove home-generated pharmaceutical waste, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances at a licensed hazardous waste incinerator, provide a certificate of destruction, and provide weight of materials collected. Do not allow home-generated pharmaceutical wastes that are hazardous waste (e.g. chemotherapy drugs) to be stored longer than 90 days at the facility as required for the management of hazardous waste.

d. Medical Prescriber Staff - No physician, dentist, veterinarian or other prescriber or the staff in these offices may accept home-generated pharmaceutical waste directly from consumers. It is the consumer's responsibility to deposit the items into the secured locked container. A prescriber may assist consumers with the identification of drugs.

8. Container Security – It is the responsibility of the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to limit diversion and theft opportunities and not allow staff or the entity overseeing the program from having access to the contents. Containers at permanent locations shall either be locked and positioned so they are not moveable or stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

The bins shall require two keys-one in the possession of the collection site's designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner: a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.

Every collection site that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported with 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. Essential Equipment and Supplies

a. <u>Pharmacies, Physicians, Veterinarians and Other Prescribers' Offices and Police Stations</u> – The following are examples of the types of equipment and supplies that shall be provided: caged, lockable secure containers, lockable kiosks, lockable steel bins, refurbished lockable mail boxes with an internal container. These types of collection containers shall be located near a building entrance or in a lobby that allows people to drop off home-generated pharmaceuticals and not be able to retrieve them, in order to prevent theft. Other supplies include black markers to cover up personal data, signage informing the public about what can and shall not be collected.

b. <u>Permanent HHW Collection Facility Equipment</u> – The following equipment and supplies shall be provided: four container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gallon plastic container for mercury items), gloves, indelible markers, and sharps container and/or mail back sharps disposal kit.

10. Budget – In order to ensure that the program is properly run, a budget estimate should be developed so that the program is free for the public to dispose of unused and unwanted home-generated pharmaceuticals at the point of disposal. In doing so the facility will need to determine who will pay for the collection and disposal of home-generated pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected.

11. Education and Advertising - Collection locations operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. Educational materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceuticals. Operators shall develop and distribute materials advertising the availability of permanent collection programs. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating jurisdictions, movie theater advertisements, advertisements on buses and bus stops, print ads in recycling guides, or English and multi-lingual public service announcements.

Collection location operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection location:

a. List what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).

b. All home-generated pharmaceutical waste must stay in their original containers; and

c. Patient name and any other personal information must be rendered unreadable on the prescription label, before turning items in for collection. Blacking out with a Sharpie or other marker is suggested. Leave the name of the drug on the container.

12. Data Collection - Data shall be kept on the total number of pounds collected, the number of residents utilizing the collection facility, and when possible, the types of materials collected for further study and analysis. Examples of collection forms can be accessed at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com. Security and confidentiality measures must be taken when retaining this data.

13. Site Visits to Collection Sites –For programs developed and overseen by public entities, those public entities shall visit collection locations periodically to help assure that procedures are being adhered to. A collection site shall make its premises available for inspection by government agencies with jurisdiction in this area.

II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government-Sponsored One Time or Periodic Collection Events

Although permanent collection programs are the preferred method to collect and properly manage home-generated pharmaceuticals, some jurisdictions such as Tuolumne County, Fresno County, City and County of Santa Cruz, and the City of Watsonville provide One-time or Periodic Collection Events. Jurisdictions offering one-time events shall adhere to the following requirements:

1. Collection Site - Access to the location must be restricted to only consumers dropping off home-generated pharmaceuticals. The designated operator shall observe consumers dropping off home-generated pharmaceuticals and shall ensure that none of the home-generated pharmaceuticals wastes are stolen. If any theft is observed or suspected, the operator shall contact the appropriate law enforcement agency and the Local Enforcement Agency of CDPH.

    a. <u>Pharmacist</u> (if a one day event is at a facility other than a pharmacy) - Pharmacists are recommended to be present at the event and must be licensed and in good standing with the California State Board of Pharmacy.

    b. <u>Dedicated Collection Area</u> - If the collection site is at an HHW facility, the facility must provide room for additional hazardous waste containers.

    c. <u>Law Enforcement</u> - Law enforcement may participate in a collection event to provide security for event personnel; this is optional at the discretion of collection organizers and not required for all events. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances from the consumer. If controlled substances will be accepted, the operator of the event shall ask the law enforcement agency that is providing the officer if the agency has any specific requirements that the event

must adhere to. For example, the law enforcement agency may specify the type of packaging that the drugs must be contained in to be accepted into their evidence locker, or if the containers the collection event will provide, are adequate for the law enforcement agency purposes. For controlled substances only, law enforcement must be on site at all times be and able to see the collection and movement of the home-generated pharmaceutical wastes from the public to the collection location. Law enforcement must be able to see the transfer of home-generated pharmaceutical wastes from vehicles to the collection containers. The operator shall coordinate with law enforcement to determine the appropriate position for law enforcement to be stationed.

2. Government Agency Authorization- Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection.   All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.

3. Medical/Hazardous Waste Hauler/Disposal Arrangements - Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at http:www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. What Can and Cannot Be Collected
    a. These programs provide for the collection and disposal of home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste.

b. Sharps in approved containers may be accepted at collection sites, but shall not be placed in the same containers as the home-generated pharmaceutical waste.

c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall <u>not</u> be accepted.

c. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to properly collect, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drug and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.

5. Signage – Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.) Home-generated pharmaceutical wastes shall be segregated for storage and, when placed in a container or secondary container, that container shall be labeled with the words "INCINERATION ONLY" or other labels approved by the CDPH on the lid and on the sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to container location. During periods of non-operation this sign shall be removed and the container shall be stored in a secure intermediate storage area.

Signage should also show how to deposit pharmaceuticals into the secured container, since staff cannot assist the consumers. The signage should also advise consumers to remove personal information from the medicine containers. In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer to participate in a take back program.

6. How Home-Generated Pharmaceuticals Shall Be Collected

Advertise where the event will take place, when it will take place, the hours of the event, and who to contact for more information. If home-generated pharmaceuticals are kept in the original, labeled container, personal information shall be removed or marked out. The containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site are not to assist consumers in placing home-generated pharmaceuticals in the bins. This is the obligation of the consumer. The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase

home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances – If Home-generated pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they shall be emptied from their containers by the consumer into the secured bin/container. Collection site staff may assist a consumer in opening a container but shall not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

b. Storage – A collection site shall not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated pharmaceutical waste shall not be placed or commingled with expired, recalled or other quarantined drugs in the possession of a collection site. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in approved containers, cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in approved container and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.

d. Chain of Custody- When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the owner of the pharmaceutical waste and is responsible for assuring that it is stored, transported, and disposed of in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other

security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and hauler number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. Staffing
The following staff are required at collection sites to implement the specified tasks:

a. <u>Greeter</u> - direct people to the collection location and answer questions. Greeters can also screen incoming people and wastes for problems. If the event is large enough, radios are useful.

b. <u>Law Enforcement Staff</u> - to provide security, take possession of controlled substances after determination by a pharmacist, transport controlled substances to evidence storage locker, document the collection of controlled substances, and arrange for and ensure U.S. Drug Enforcement Agency authorized witnessed destruction of controlled substances. Law enforcement staff can also provide crowd control and watch for problem people. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with the law enforcement agency providing an officer for the event, whether they have requirements for the type of packaging the drugs must be contained in to be accepted into their evidence locker, or if containers the collection event will provide are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel. This is optional at the discretion of collection organizers and not required for all events.

c. <u>Pharmacist </u>- to determine if a medication is a controlled substance, identify non-labeled home-generated pharmaceutical waste, inventory controlled substances, witness, and sign the inventory.

d. <u>Hazardous Waste Personnel</u> - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste on the same day as the event, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, provide weight of materials collected, and complete data entry.

8. Container Security – It is the responsibility of the entity overseeing the collection event to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be

deposited into secured containers to limit diversion and theft opportunities and not allow staff or the entity overseeing the event from having access to the contents. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

Every collection event that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported with 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. Essential Equipment and Supplies

a. Tools for counting home-generated pharmaceutical waste (pharmacist should provide this);
b. Hazardous waste containers;
c. Gloves (Disposable latex or non-latex);
d. Sealable plastic bags (One-gallon and snack size, with external slide mechanism);
e. Extension cords, grounded;
f. Survey forms (examples can be found at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com);
g. Indelible markers;
h. Packing tape;
i. Containers- Check with your contracted medical or hazardous waste hauler for appropriate containers; and
j. Sharps disposal container -Provide sharps containers to collect sharps if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point.
k. Personal protective equipment – All staff must wear gloves (latex or non-latex) at all times when handling pharmaceutical waste. This is important as the containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) must be avoided. Wearing facemasks should be considered, especially for the pharmacist who is doing the physical determination of the home-generated pharmaceutical waste. Do not eat or drink directly in the area that the home-generated pharmaceutical wastes are being collected. Discard used gloves.

10. Budget - An estimate of the budget should be developed and the program must be free to the public to dispose of unused and unwanted home-generated pharmaceuticals.

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11. Education and Advertising – Collection event operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. These materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceutical waste. Event operators shall develop and distribute materials advertising for the collection event. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating cities, movie theatre advertisements, advertisements on buses and at bus stops, print ads in recycling guides or English and multi-lingual public service announcements.

Collection event operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection event:

    a. List what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste.

    b. All home-generated pharmaceutical waste must stay in their original containers.

12. Data Collection - Determine amounts of home-generated pharmaceuticals collected along with the number of donators. If time allows, determine the types and amounts of home-generated pharmaceuticals collected. This information could be used for further studies and policy recommendations. Security and confidentiality measures should be taken when retaining this data.

Each collection event must have a log specific to that collection event. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection event (b) the address, phone number and location number where the event was located; (c) the date the collection event took place; (d) the names of at least one person from the event who witnessed the pickup by the licensed waste hauler (e) the name of the waste hauler's staff person who picked up the collected waste; (f) the weight of home-generated pharmaceutical waste removed from collection event; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals. The log should indicate the name, address and hauler number of waste hauler taking the drugs. These records shall be kept for 3 years after the life of the collection event by the host agency.

13. Site Visits to Collection Sites – The event organizer shall inspect the location to ensure compliance with all requirements. The CIWMB may request a report summarizing the activities of each collection location including amounts of home-generated pharmaceutical waste collected and the number of days in operation as a collection location for home-generated pharmaceuticals.

III. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs Through a Mail Back Program

In some jurisdictions mailing back used and unused home-generated pharmaceuticals may be the only or most convenient option for the proper management of these items. An example is the State of Maine, which uses pre-paid mailing envelopes available at pharmacies, doctors' offices and post offices. In addition, some pharmaceutical companies, such as Celgene, will take back their own home-generated pharmaceuticals via mail. Celgene allows patients to return unused drugs such as thalidomide purchased from the company, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

Locations for Mail-Back Programs shall only be allowed if the following requirements are met:

1. Each entity overseeing either a Mail-Back Location or Mail-Back Program shall ensure that the home-generated pharmaceutical waste is destroyed in accordance with applicable regulations. CIWMB may request that each Mail-Back Location or Program provide information on the amounts of home-generated pharmaceuticals received and destroyed.

2. Determine locations where home-generated pharmaceuticals can be mailed for proper management and destruction. These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. In addition, these facilities must be able to provide data on the amounts of home-generated pharmaceuticals received and destroyed.

3. Operators of mail-back programs shall obtain self-sealing pre-addressed and pre-stamped envelopes that are approved by the U.S. Postal Service for containment and transportation of home-generated pharmaceutical waste. The envelopes shall also include an instruction sheet on how to package and send the home-generated pharmaceuticals.

4. Operators of mail back programs shall provide postage-paid envelopes to pharmacies to be provided to consumers that will be utilized for the mailing and destruction of unused and expired home-generated pharmaceuticals.

5. Envelopes shall be tracked to assure that all envelopes are used for their intended purposes and that all of the home-generated pharmaceuticals get to the destruction facility.

6. Operator shall advertise its mail back program at pharmacies, convalescent homes, and retirement homes in order to inform potential users of the program of its availability and requirements for participation.

7. The operator shall review data on the amounts of home-generated pharmaceuticals collected to assure that the amounts are increasing and shall make changes to the program as needed to the program to assure continued growth.

Appendix I-Definitions

1. Controlled Substance-any substance listed in Chapter 2 (commencing with Section 11053) of Davison 10 of the CA Health & Safety Code.

2. Event – Include programs and one- time events for the collection of home-generated pharmaceutical waste to assure appropriate disposal of these items.

3. Collection Programs – include permanent collection programs, temporary collection programs, and mail back collection programs

4. Model Program - CIWMB a[p[proved program through which the public may return unused or expired home-generated that meets statutory criteria.

5. Over the Counter Drug - a non-prescription drug a defined per CA Business & Professions Code Section 4025.1 which states "non-prescription drugs" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the laws and rules of this state and the federal government.

6. Collection Facility - any entity CIWMB finds appropriate to implement or evaluate a model home-generated pharmaceutical waste program. The participant must agree to participate as a model program. Entities that may qualify to participate:

    a. Governmental entities (includes police and sheriff's stations, public/environmental health agencies and HHW facilities);
    b. Pharmacies with active unrestricted licenses from the California State Board of Pharmacy;
    c. Other Physician and other licensed health care prescribers' offices; and
    d. Healthcare Collection Sites that are licensed by the Department of Consumer Affairs

7. Pharmaceutical Waste - In this document it is considered to be a prescription drug dispensed to a consumer or a non-prescription item, no longer wanted or need by the consumer and includes home-generated pharmaceuticals in many delivery systems, such as pills, liquids, and inhalers.

8. Prescription Drug - is a dangerous drug as defined per California Business and Professions Code Section 4022 which means any drug unsafe for self-use in humans or animals, without the oversight of a licensed prescriber and includes the following:

    (a) any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription, "Rx only", or words of similar import.
    (b) any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to CA Business & Professions Code Section 4006.

Summary of Existing Pharmaceutical Programs Meeting SB 966 Model Criteria						
Pharmaceutical Collection Programs	**SB 966 Model Criteria**					
	Safe Disposal of Drugs	No Cost for Disposal	Protection of Public Health	Documents Pharmaceuticals Collected	Prevents Diversion of Drugs	Educational and Outreach Materials
San Mateo County	X	X	X	X	X	
Sonoma County Water Agency	X	X	X	X	X	X
Teleosis Institute	X	X	X	X	X	X
City of Santa Cruz	X	X	X	X	X	X
Crescent Healthcare	X		X			X
County of Santa Clara	X	X	X	X	X	
City of Santa Rosa	X	X	X	X	X	X
Tulare County Environmental Health	X	X	X		X	
Santa Barbara County	X	X	X		X	X

Pharmaceutical Collection Program	Safe Disposal of Drugs	No Cost for Disposal	Protection of Public Health	Documents Pharmaceuticals Collected	Prevents Diversion of Drugs	Educational and Outreach Materials
County of Fresno	X	X	X		X	
San Benito County Integrated Waste Management	X	X	X		X	
East Bay Municipal Utility District	X	X	X	X	X	X
Marin County	X	X	X	X	X	X
County of Tuolumne	X	X	X		X	
City of Fontana	X	X	X		X	
City of Los Angeles	X	X	X	X	X	X
City of Folsom	X	X	X		X	
City of West Hollywood	X	X	X			X
City of Millbrae	X	X	X		X	X
Leiter's Pharmacy	X	X	X	X	X	X
County of Ventura	X	X	X		X	X
City of Calabasas, Public Works Dept.	X	X	X			X
San Luis Obispo County	San Luis Obispo County submitted a survey, but have not implemented a collection program at this time.					

City of Indian Wells	X	X	X		X	X
Pharmaceutical Collection Program	**Safe Disposal of Drugs**	**No Cost for Disposal**	**Protection of Public Health**	**Documents Pharmaceuticals Collected**	**Prevents Diversion of Drugs**	**Educational and Outreach Materials**
Delta Diablo Sanitation District	X	X	X		X	
Celgene Corporation	X	X	X	X	X	X
Other State's Collection Programs						
Will County, IL	X	X	X		X	X
Clark County, WA	X	X	X		X	X
Kendall County, IL	X	X	X		X	X
La Crosse, WI	X	X	X		X	X
Olmsted Falls, OH	X	X	X		X	X
Pugent Sound Area, Washington State	X	X	X	X	X	
Allen County, IN	X	X	X			X
Chicago, IL	X		X	X		X
Earth Keeper Initiative, Upper Penninsula, MI	X	X	X	X	X	X

Pharmaceutical Collection Program	Safe Disposal of Drugs	No Cost for Disposal	Protection of Public Health	Documents Pharmaceuticals Collected	Prevents Diversion of Drugs	Educational and Outreach Materials
Milwaukee, WI, Metropolitan Sewarage District	X	X	X	X	X	X
Monroe County, IN	X	X	X	X	X	X
Montague, MA		X	X	X		
South Hadley, MA		X	X	X	X	
South Portland, ME		X	X	X	X	X
Saugamon County, IL	X	X	X	X	X	X
Safe Medicine Disposal for ME Program	X	X	X	X	X	X
Alachua County Environmental Protection Dept., FL	X	X	X	X	X	X
West Lafayette Go Greener, IN	X	X		X	X	
Newberg, OR	X	X	X		X	
North Carolina	An Internet search and contacting the North Carolina Dept. of the Environment and Natural Resources did not reveal any active programs for the collection of unused an unwanted pharmaceuticals.					

Pharmaceutical Collection Program	Safe Disposal of Drugs	No Cost for Disposal	Protection of Public Health	Documents Pharmaceuticals Collected	Prevents Diversion of Drugs	Educational and Outreach Materials
Other Countries' Collection Programs						
Australia	X	X	X	X	X	
British Columbia, Canada	X	X	X	X	X	X
France	X	X	X	X	X	X

SENATE BILL   No. 26

Introduced by Senator Simitian

December 1, 2008

An act to add Sections 4001.2, 4068.1, and 4146 to the Business and Professions Code, to amend Sections 117700, 117935, 117945, 117960, 118000, 118040, 118147, and 118165 of, and to add Sections 117642, 117669, 117748, 117904.5, 118031, and 118041 to, the Health and Safety Code, and to amend Section 47200 of the Public Resources Code, relating to pharmaceutical waste.

SB 26, as introduced, Simitian. Home-generated pharmaceutical waste.

The existing Pharmacy Law establishes the California State Board of Pharmacy, prescribes the licensing, regulatory, and disciplinary functions of the board, and authorizes the board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Existing law, the California Integrated Waste Management Act of 1989, requires the California Integrated Waste Management Board to adopt regulations that set forth minimum standards for solid waste management and require assurance of financial ability to pay for specified injury and property damage claims resulting from the operation of a disposal facility. The act requires the board to expend moneys from

the Solid Waste Management Account in the Integrated Waste Management Fund, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, as provided.

This bill would require that local programs to help prevent the disposal of home-generated sharps waste and home-generated pharmaceutical waste at disposal sites also be included among the types of local programs that may be funded by such a grant.

Existing law, the Medical Waste Management Act, requires the State Department of Public Health to regulate the management and handling of medical waste, as defined. Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.

This bill would also exclude home-generated pharmaceutical waste, as defined, from the definition of medical waste.

Existing law regulates the methods of consolidating, storing, and transporting medical waste and home-generated sharps waste. Violation of these provisions is a crime.

This bill would regulate consolidation points for home-generated pharmaceutical waste, as defined, as well as transportation and disposal of that waste by both hazardous waste haulers and common carriers, as defined. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1   SECTION 1. Section 4001.2 is added to the Business and
2 Professions Code, to read:
3   4001.2. To further the purposes of Section 4001.1, and to
4 protect the public from hazards caused by the improper
5 management and disposal of waste drugs and devices, the

1 California State Board of Pharmacy shall coordinate with other
2 state agencies, local governments, drug manufacturers, and
3 pharmacies to develop sustainable, efficient policies and programs
4 to properly manage pharmaceutical wastes and the disposal of
5 these wastes.
6   SEC. 2. Section 4068.1 is added to the Business and Professions
7 Code, to read:
8   4068.1. A pharmacy may accept the return of home-generated
9 pharmaceutical waste, as defined in Section 117769 of the Health
10 and Safety Code, from the public.
11   SEC. 3. Section 4146 is added to the Business and Professions
12 Code, to read:
13   4146. A pharmacy may accept the return of home-generated
14 sharps waste, as defined in Section 117671 of the Health and Safety
15 Code, from a person if the waste is contained in a sharps container.
16   SEC. 4. Section 117642 is added to the Health and Safety Code,
17 to read:
18   117642. "Common carrier" means a person or company that
19 hauls for hire goods, including, but not limited to, pharmaceutical
20 waste or home-generated pharmaceutical waste. Home-generated
21 pharmaceutical waste must have been consolidated at a location
22 approved by the enforcement agency as a home-generated
23 pharmaceutical waste consolidation point.
24   SEC. 5. Section 117669 is added to the Health and Safety Code,
25 to read:
26   117669. "Home-generated pharmaceutical waste" means
27 prescribed and over-the-counter drugs derived from a household.
28   SEC. 6. Section 117700 of the Health and Safety Code is
29 amended to read:
30   117700. Medical waste does not include any of the following:
31   (a) Waste generated in food processing or biotechnology that
32 does not contain an infectious agent as defined in Section 117675.
33   (b) Waste generated in biotechnology that does not contain
34 human blood or blood products or animal blood or blood products
35 suspected of being contaminated with infectious agents known to
36 be communicable to humans.
37   (c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears,
38 or vomitus, unless it contains fluid blood, as provided in
39 subdivision (d) of Section 117635.

1   (d) Waste which *that* is not biohazardous, such as paper towels,
2 paper products, articles containing nonfluid blood, and other
3 medical solid waste products commonly found in the facilities of
4 medical waste generators.
5   (e) Hazardous waste, radioactive waste, or household waste,
6 including, but not limited to, home-generated sharps waste, as
7 defined in Section 117671, *and home-generated pharmaceutical*
8 *waste, as defined in Section 117669.*
9   (f) Waste generated from normal and legal veterinarian,
10 agricultural, and animal livestock management practices on a farm
11 or ranch.
12   SEC. 7. Section 117748 is added to the Health and Safety Code,
13 to read:
14   117748. "Pharmaceutical waste" means any pharmaceutical,
15 prescription, or over-the-counter human or veterinary drug,
16 including, but not limited to, a drug, as defined in Section 109925,
17 or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec.
18 321(g)(1)) that meets any of the following requirements:
19   (a) The drug may no longer be sold or dispensed because it has
20 expired.
21   (b) The drug can no longer be used for its intended purpose.
22   (c) The drug has been discarded.
23   (d) The drug has been consolidated at a location approved by
24 the enforcement agency as a home-generated pharmaceutical waste
25 consolidation point.
26   SEC. 8. Section 117904.5 is added to the Health and Safety
27 Code, to read:
28   117904.5. (a) In addition to the consolidation points authorized
29 pursuant to Section 118147, the enforcement agency may approve
30 a location as a point of consolidation for the collection of
31 home-generated pharmaceutical waste. These locations may
32 include, but are not limited to, pharmacies, heath care facilities,
33 veterinarian offices, clinics, household hazardous waste programs,
34 solid waste facilities, senior centers, or government offices.
35   (b) A consolidation location approved pursuant to this section
36 shall be known as a home-generated pharmaceutical waste
37 consolidation point.
38   (c) A home-generated pharmaceutical waste consolidation point
39 is not subject to the requirements of Chapter 9 (commencing with
40 Section 118275) of Part 14 of Division 4, to the permit

1 requirements of this part, or to any permit or registration fees, with
2 regard to the activity of consolidating home-generated
3 pharmaceutical waste pursuant to this section.
4   (d) A home-generated pharmaceutical waste consolidation point
5 shall comply with all of the following requirements:
6   (1) It shall be approved by the enforcement agency for this
7 purpose.
8   (2) The home-generated pharmaceutical waste collected and
9 consolidated at the facility shall be collected and contained in a
10 leak-resistant container and placed in a secure area that does not
11 allow the waste to be accessed or salvaged by unauthorized persons.
12   (3) Containers ready for disposal shall not be held for more than
13 90 days without the written approval of the enforcement agency.
14   (e) An operator of a home-generated pharmaceutical waste
15 consolidation point that is approved pursuant to this section shall
16 not be considered a generator of that waste.
17   (f) The end disposal facility that treats the home-generated
18 pharmaceutical waste shall maintain the tracking documents
19 required by Section 118040 or 118041, as applicable, and Section
20 118165 with regard to the pharmaceutical waste.
21   (g) Nothing in this section shall exempt any person from any
22 federal or state law governing pharmaceuticals.
23   SEC. 9. Section 117935 of the Health and Safety Code is
24 amended to read:
25   117935. Any small quantity generator required to register with
26 the enforcement agency pursuant to Section 117930 shall file with
27 the enforcement agency a medical waste management plan, on
28 forms prescribed by the enforcement agency containing, but not
29 limited to, all of the following:
30   (a) The name of the person.
31   (b) The business address of the person.
32   (c) The type of business.
33   (d) The types, and the estimated average monthly quantity, of
34 medical waste generated.
35   (e) The type of treatment used onsite.
36   (f) The name and business address of the registered hazardous
37 waste hauler used by the generator for backup treatment and
38 disposal, for waste when the onsite treatment method is not
39 appropriate due to the hazardous or radioactive characteristics of
40 the waste, or the name of the registered hazardous waste hauler

1 used by the generator to have untreated medical waste removed
2 for treatment and disposal, *and, if applicable, the name of the*
3 *common carrier used by the generator to transport pharmaceutical*
4 *waste offsite for treatment and disposal.*
5   (g) A statement indicating that the generator is hauling the
6 medical waste generated in his or her business pursuant to Section
7 118030 and the name and any business address of the treatment
8 and disposal facilities to which the waste is being hauled, if
9 applicable.
10   (h) The name and business address of the registered hazardous
11 waste hauler service provided by the building management to
12 which the building tenants may subscribe or are required by the
13 building management to subscribe and the name and business
14 address of the treatment and disposal facilities used, if applicable.
15   (i) A statement certifying that the information provided is
16 complete and accurate.
17   SEC. 10. Section 117945 of the Health and Safety Code is
18 amended to read:
19   117945. Small quantity generators who are not required to
20 register pursuant to this chapter shall maintain on file in their office
21 all of following:
22   (a) An information document stating how the generator contains,
23 stores, treats, and disposes of any medical waste generated through
24 any act or process of the generator.
25   (b) Records of any medical waste transported offsite for
26 treatment and disposal, including the quantity of waste transported,
27 the date transported, and the name of the registered hazardous
28 waste hauler or individual hauling the waste pursuant to Section
29 118030, *or the name of the common carrier hauling*
30 *pharmaceutical waste pursuant to Section 118031.* The small
31 quantity generator shall maintain these records for not less than
32 two years.
33   SEC. 11. Section 117960 of the Health and Safety Code is
34 amended to read:
35   117960. Any large quantity generator required to register with
36 the enforcement agency pursuant to Section 117950 shall file with
37 the enforcement agency a medical waste management plan, on
38 forms prescribed by the enforcement agency containing, but not
39 limited to, all of the following:
40   (a) The name of the person.

1   (b) The business address of the person.
2   (c) The type of business.
3   (d) The types, and the estimated average monthly quantity, of
4 medical waste generated.
5   (e) The type of treatment used onsite, if applicable. For
6 generators with onsite medical waste treatment facilities, including
7 incinerators or steam sterilizers or other treatment facilities as
8 determined by the enforcement agency, the treatment capacity of
9 the onsite treatment facility.
10   (f) The name and business address of the registered hazardous
11 waste hauler used by the generator to have untreated medical waste
12 removed for treatment, if applicable, *or the name of the common*
13 *carrier hauling pharmaceutical waste pursuant to Section 118031.*
14   (g) The name and business address of the registered hazardous
15 waste hauler service provided by the building management to
16 which the building tenants may subscribe or are required by the
17 building management to subscribe, if applicable.
18   (h) The name and business address of the offsite medical waste
19 treatment facility to which the medical waste is being hauled, if
20 applicable.
21   (i) An emergency action plan complying with regulations
22 adopted by the department.
23   (j) A statement certifying that the information provided is
24 complete and accurate.
25   SEC. 12. Section 118000 of the Health and Safety Code is
26 amended to read:
27   118000. (a) Except as otherwise exempted pursuant to Section
28 118030 *or 118031*, all medical waste transported to an offsite
29 medical waste treatment facility shall be transported in accordance
30 with this chapter by a registered hazardous waste transporter issued
31 a registration certificate pursuant to Chapter 6 (commencing with
32 Section 118025) and Article 6.5 (commencing with Section
33 25167.1) of Chapter 6.5 of Division 20. A hazardous waste
34 transporter transporting medical waste shall have a copy of the
35 transporter's valid hazardous waste transporter registration
36 certificate in the transporter's possession while transporting
37 medical waste. The transporter shall show the certificate, upon
38 demand, to any enforcement agency personnel or authorized
39 employee of the Department of the California Highway Patrol.

1   (b) Except for small quantity generators transporting medical
2 waste pursuant to Section 118030 *or small quantity generators or*
3 *common carriers transporting home-generated pharmaceutical*
4 *waste pursuant to Section 118031*, medical waste shall be
5 transported to a permitted offsite medical waste treatment facility
6 or a permitted transfer station in leak-resistant and fully enclosed
7 rigid secondary containers that are then loaded into an enclosed
8 cargo body.
9   (c) A person shall not transport medical waste in the same
10 vehicle with other waste unless the medical waste is separately
11 contained in rigid containers or kept separate by barriers from
12 other waste, or unless all of the waste is to be handled as medical
13 waste in accordance with this part.
14   (d) Medical waste shall only be transported to a permitted
15 medical waste treatment facility, or to a transfer station or another
16 registered generator for the purpose of consolidation before
17 treatment and disposal, pursuant to this part.
18   (e) Facilities for the transfer of medical waste shall be annually
19 inspected and issued permits in accordance with the regulations
20 adopted pursuant to this part.
21   (f) Any persons manually loading or unloading containers of
22 medical waste shall be provided by their employer at the beginning
23 of each shift with, and shall be required to wear, clean and
24 protective gloves and coveralls, changeable lab coats, or other
25 protective clothing. The department may require, by regulation,
26 other protective devices appropriate to the type of medical waste
27 being handled.
28   SEC. 13. Section 118031 is added to the Health and Safety
29 Code, to read:
30   118031. Pharmaceutical waste may be shipped by a common
31 carrier if the generator or home-generated pharmaceutical waste
32 consolidation point meets the following requirements:
33   (a) The facility shall maintain documentation as required in
34 Sections 118040 and 118041.
35   (b) The waste products are transported to any of the following:
36   (1) A medical waste facility.
37   (2) A hazardous waste facility.
38   (3) A reverse distributor, with the final destination of a medical
39 or hazardous waste facility.

1   SEC. 14. Section 118040 of the Health and Safety Code is
2 amended to read:
3   118040. (a) Except with regard to sharps waste consolidated
4 by a home-generated sharps consolidation point approved pursuant
5 to Section 117904, *pharmaceutical waste or home-generated*
6 *pharmaceutical waste consolidated by a home-generated*
7 *pharmaceutical waste consolidation point approved pursuant to*
8 *Section 117904.5, or home-generated pharmaceutical waste*
9 *transported pursuant to Section 118031,* a hazardous waste
10 transporter or generator transporting medical waste shall maintain
11 a completed tracking document of all medical waste removed for
12 treatment or disposal. A hazardous waste transporter or generator
13 who transports medical waste to a facility, other than the final
14 medical waste treatment facility, shall also maintain tracking
15 documents which show the name, address, and telephone number
16 of the medical waste generator, for purposes of tracking the
17 generator of medical waste when the waste is transported to the
18 final medical waste treatment facility. At the time that the medical
19 waste is received by a hazardous waste transporter, the transporter
20 shall provide the medical waste generator with a copy of the
21 tracking document for the generator's medical waste records. The
22 transporter or generator transporting medical waste shall maintain
23 its copy of the tracking document for three years.
24   (b) The tracking document shall include, but not be limited to,
25 all of the following information:
26   (1) The name, address, telephone number, and registration
27 number of the transporter, unless transported pursuant to Section
28 118030.
29   (2) The type and quantity of medical waste transported.
30   (3) The name, address, and telephone number of the generator.
31   (4) The name, address, telephone number, permit number, and
32 the signature of an authorized representative of the permitted
33 facility receiving the medical waste.
34   (5) The date that the medical waste is collected or removed from
35 the generator's facility, the date that the medical waste is received
36 by the transfer station, the registered large quantity generator, or
37 point of consolidation, if applicable, and the date that the medical
38 waste is received by the treatment facility.
39   (c) Any hazardous waste transporter or generator transporting
40 medical waste in a vehicle shall have a tracking document in his

1 or her possession while transporting the medical waste. The
2 tracking document shall be shown upon demand to any
3 enforcement agency personnel or officer of the Department of the
4 California Highway Patrol. If the medical waste is transported by
5 rail, vessel, or air, the railroad corporation, vessel operator, or
6 airline shall enter on the shipping papers any information
7 concerning the medical waste that the enforcement agency may
8 require.
9   (d) A hazardous waste transporter or a generator transporting
10 medical waste shall provide the facility receiving the medical waste
11 with the original tracking document.
12   (e) Each hazardous waste transporter and each medical waste
13 treatment facility shall provide tracking data periodically and in a
14 format as determined by the department.
15   (f) Medical waste transported out of state shall be consigned to
16 a permitted medical waste treatment facility in the receiving state.
17 If there is no permitted medical waste treatment facility in the
18 receiving state or if the medical waste is crossing an international
19 border, the medical waste shall be treated in accordance with
20 Chapter 8 (commencing with Section 118215) prior to being
21 transported out of the state.
22   SEC. 15. Section 118041 is added to the Health and Safety
23 Code, to read:
24   118041. (a) A person transporting pharmaceutical waste shall
25 maintain a completed tracking document of all pharmaceutical
26 waste removed for treatment or disposal. A copy of the tracking
27 document shall be included with the container holding the
28 pharmaceutical waste.
29   (b) The tracking document shall include, but not be limited to,
30 all of the following information:
31   (1) The name, address, and telephone number of the generator.
32   (2) Specific information indicating that pharmaceutical waste
33 is being transported.
34   (3) The name, address, and telephone number of the person
35 transporting the waste.
36   (4) The name, address, telephone number, and permit number
37 of the permitted treatment facility or transfer station to which the
38 pharmaceutical waste is being sent.

1   (5) The date that the pharmaceutical waste was collected or
2 removed from the generator or home-generated pharmaceutical
3 waste consolidation point.
4   (c) A person tracking pharmaceutical waste shall have a tracking
5 document for the waste in his or her possession while transporting
6 the waste. The tracking document shall be shown, upon demand,
7 to any enforcement agency personnel or officer of the Department
8 of the California Highway Patrol.
9   (d) A medical waste treatment facility and transfer station shall
10 date and sign a copy of the tracking document upon receipt,
11 periodically provide data in a format determined by the department,
12 and shall maintain a copy of the tracking document for three years.
13   (e) This section does not prohibit the use of a single document
14 to verify the return of more than one container to a parent
15 organization or another health care facility for the purpose of
16 consolidation before treatment and disposal of the pharmaceutical
17 waste over a period of time, if the form or log is maintained in the
18 files of the parent organization or other health care facility that
19 receives the waste.
20   (f) Pharmaceutical waste transported out of state shall be
21 consigned to a permitted medical waste treatment facility in the
22 receiving state. If there is no permitted medical waste treatment
23 facility in the receiving state, or if the waste is crossing an
24 international border, the home-generated pharmaceutical waste
25 shall be treated pursuant to Section 118222 prior to being
26 transported out of state.
27   SEC. 16. Section 118147 of the Health and Safety Code is
28 amended to read:
29   118147. Notwithstanding any other provision of this chapter,
30 a registered medical waste generator, which is a facility specified
31 in subdivisions (a) and (b) of Section 117705, may accept
32 home-generated sharps waste *and home-generated pharmaceutical*
33 *waste*, to be consolidated with the facility's medical waste stream,
34 subject to all of the following conditions:
35   (a) The generator of the *home-generated* sharps waste *or*
36 *home-generated pharmaceutical waste*, a member of the
37 generator's family, or a person authorized by the enforcement
38 agency transports the sharps waste *or pharmaceutical waste* to the
39 medical waste generator's facility.

1   (b) The *home-generated* sharps waste *or home-generated*
2 *pharmaceutical waste* is accepted at a central location at the
3 medical waste generator's facility.
4   (c) A reference to, and a description of, the actions taken
5 pursuant to this section are included in the facility's medical waste
6 management plan adopted pursuant to Section 117960.
7   SEC. 17. Section 118165 of the Health and Safety Code is
8 amended to read:
9   118165. On and after April 1, 1991, all persons operating a
10 medical waste treatment facility shall maintain individual records
11 for a period of three years and shall report or submit to the
12 enforcement agency upon request, all of the following information:
13   (a) The type of treatment facility and its capacity.
14   (b) All treatment facility operating records.
15   (c) Copies of the tracking documents for all medical waste it
16 receives for treatment from offsite generators or from hazardous
17 waste haulers *or common carriers, pursuant to Section 118041.*
18   SEC. 18. Section 47200 of the Public Resources Code is
19 amended to read:
20   47200. (a) The board shall expend funds from the account,
21 upon appropriation by the Legislature, for the making of grants to
22 cities, counties, or other local agencies with responsibility for solid
23 waste management, and for local programs to help prevent the
24 disposal of *home-generated sharps waste, as defined in Section*
25 *117671 of the Health and Safety Code, home-generated*
26 *pharmaceutical waste, as defined in Section 117669 of the Health*
27 *and Safety Code, and* hazardous wastes at disposal sites, including,
28 but not limited to, programs to expand or initially implement
29 household hazardous waste programs. In making grants pursuant
30 to this section, the board shall give priority to funding programs
31 that provide for the following:
32   (1) New programs for rural areas, underserved areas, and for
33 small cities.
34   (2) Expansion of existing programs to provide for the collection
35 of additional waste types, innovative or more cost-effective
36 collection methods, or expanded public education services.
37   (3) Regional household hazardous waste programs.
38   (b) (1) The total amount of grants made by the board pursuant
39 to this section shall not exceed, in any one fiscal year, three million
40 dollars ($3,000,000).

1   (2) Notwithstanding paragraph (1), the total amount of grants
2 made by the board pursuant to this section may exceed three
3 million dollars ($3,000,000) but shall not exceed six million dollars
4 ($6,000,000), in any one fiscal year, if sufficient funds are
5 appropriated from the Integrated Waste Management Account for
6 this purpose.
7   SEC. 19. No reimbursement is required by this act pursuant to
8 Section 6 of Article XIII B of the California Constitution because
9 the only costs that may be incurred by a local agency or school
10 district will be incurred because this act creates a new crime or
11 infraction, eliminates a crime or infraction, or changes the penalty
12 for a crime or infraction, within the meaning of Section 17556 of
13 the Government Code, or changes the definition of a crime within
14 the meaning of Section 6 of Article XIII B of the California
15 Constitution.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: December 2, 2008

To: Enforcement Committee

Subject: Sharps Take-Back Drug Programs in Pharmacies

Background and Update:
A related, but separate issue to the problem of how society will dispose of unwanted drug products is the issue of disposal of used sharps.

According to estimates by the California Integrated Waste Management Board, California patients use hundreds of millions of needles and syringes each year. This does not include lancets. This is a disposal issue and a public health and safety issue.

Since September 1, 2008, California law has prohibited the disposal of sharps in trash or recycling containers. I am attaching information from the Integrated Waste Management Board's Web site. Pharmacies are listed as one of the disposal locations. However, pharmacy law does not authorize pharmacies to take back sharps, unless there is a county-adopted needle exchange program in place.

At the October 2008 Board Meeting, the board approved a policy statement that:
California law does not authorize pharmacies to accept the return of sharps when appropriately contained in an approved sharps container. The board reserves its enforcement discretion about whether to intervene with any pharmacy that takes back sharps containers inappropriately. However, until this matter is fully resolved, the board does not anticipate intervening in such practices. Nevertheless, this policy may change as a result of a complaint or public safety issue.

This policy statement will be published in the January 2009 *The Script* newsletter.

Additionally, at the October 3008 Board Meeting, the board agreed to sponsor a statutory amendment to allow pharmacies to take back sharps. This proposal was proposed as an amendment to section 4146:
A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container as defined by Health and Safety Code section 117750.

Meanwhile, SB 26 (Simitian), as introduced on December 1, 2008, would specifically authorize a pharmacy to take back sharps waste (see proposed section 4146, attached).

Regarding appropriate destruction, the Department of Public Health states that:

California Health and Safety Code, Section 118286 (b)

On or after September 1, 2008, home-generated sharps waste <u>shall be transported only in a sharps container, or other containers approved by the enforcement agency,</u> and shall only be managed at any of the following:
(1) A household hazardous waste facility pursuant to Section 25218.13.
(2) A "home-generated sharps consolidation point" as defined in subdivision (b) of Section 117904.
(3) A medical waste generator's facility pursuant to Section 118147.
(4) A facility through the use of a medical waste mail-back container approved by the department pursuant to subdivision (b) of Section 118245.

The CDPH Medical Waste Management Program is recommending the use of sharps containers approved by the U.S. Food and Drug Administration (FDA).

Lastly, the issue of how and where patients return sharps and who will pay for the expense of these returns continues. Some counties (e.g., San Luis Obispo) and communities have provided grants to compensate for the expense of appropriate disposal (see attached articles).

1 California State Board of Pharmacy shall coordinate with other
2 state agencies, local governments, drug manufacturers, and
3 pharmacies to develop sustainable, efficient policies and programs
4 to properly manage pharmaceutical wastes and the disposal of
5 these wastes.
6   SEC. 2. Section 4068.1 is added to the Business and Professions
7 Code, to read:
8   4068.1. A pharmacy may accept the return of home-generated
9 pharmaceutical waste, as defined in Section 117769 of the Health
10 and Safety Code, from the public.
11   SEC. 3. Section 4146 is added to the Business and Professions
12 Code, to read:
13   4146. A pharmacy may accept the return of home-generated
14 sharps waste, as defined in Section 117671 of the Health and Safety
15 Code, from a person if the waste is contained in a sharps container.
16   SEC. 4. Section 117642 is added to the Health and Safety Code,
17 to read:
18   117642. "Common carrier" means a person or company that
19 hauls for hire goods, including, but not limited to, pharmaceutical
20 waste or home-generated pharmaceutical waste. Home-generated
21 pharmaceutical waste must have been consolidated at a location
22 approved by the enforcement agency as a home-generated
23 pharmaceutical waste consolidation point.
24   SEC. 5. Section 117669 is added to the Health and Safety Code,
25 to read:
26   117669. "Home-generated pharmaceutical waste" means
27 prescribed and over-the-counter drugs derived from a household.
28   SEC. 6. Section 117700 of the Health and Safety Code is
29 amended to read:
30   117700. Medical waste does not include any of the following:
31   (a) Waste generated in food processing or biotechnology that
32 does not contain an infectious agent as defined in Section 117675.
33   (b) Waste generated in biotechnology that does not contain
34 human blood or blood products or animal blood or blood products
35 suspected of being contaminated with infectious agents known to
36 be communicable to humans.
37   (c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears,
38 or vomitus, unless it contains fluid blood, as provided in
39 subdivision (d) of Section 117635.

1   (d) Waste which *that* is not biohazardous, such as paper towels,
2 paper products, articles containing nonfluid blood, and other
3 medical solid waste products commonly found in the facilities of
4 medical waste generators.
5   (e) Hazardous waste, radioactive waste, or household waste,
6 including, but not limited to, home-generated sharps waste, as
7 defined in Section 117671, *and home-generated pharmaceutical*
8 *waste, as defined in Section 117669.*
9   (f) Waste generated from normal and legal veterinarian,
10 agricultural, and animal livestock management practices on a farm
11 or ranch.
12   SEC. 7. Section 117748 is added to the Health and Safety Code,
13 to read:
14   117748. "Pharmaceutical waste" means any pharmaceutical,
15 prescription, or over-the-counter human or veterinary drug,
16 including, but not limited to, a drug, as defined in Section 109925,
17 or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec.
18 321(g)(1)) that meets any of the following requirements:
19   (a) The drug may no longer be sold or dispensed because it has
20 expired.
21   (b) The drug can no longer be used for its intended purpose.
22   (c) The drug has been discarded.
23   (d) The drug has been consolidated at a location approved by
24 the enforcement agency as a home-generated pharmaceutical waste
25 consolidation point.
26   SEC. 8. Section 117904.5 is added to the Health and Safety
27 Code, to read:
28   117904.5. (a) In addition to the consolidation points authorized
29 pursuant to Section 118147, the enforcement agency may approve
30 a location as a point of consolidation for the collection of
31 home-generated pharmaceutical waste. These locations may
32 include, but are not limited to, pharmacies, heath care facilities,
33 veterinarian offices, clinics, household hazardous waste programs,
34 solid waste facilities, senior centers, or government offices.
35   (b) A consolidation location approved pursuant to this section
36 shall be known as a home-generated pharmaceutical waste
37 consolidation point.
38   (c) A home-generated pharmaceutical waste consolidation point
39 is not subject to the requirements of Chapter 9 (commencing with
40 Section 118275) of Part 14 of Division 4, to the permit

ELK GROVE OK'S PICKUP SERVICE FOR NEEDLE DISPOSAL

By Loretta Kalb
lkalb@sacbee.com
The Sacramento Bee
November 19, 2008

Elk Grove residents who use hypodermic needles and other "sharps" associated with biohazardous waste have a new option for legal disposal.

They can deposit used needles in small, secure containers and then call the city's waste hauler at (916) 635-2500 to have them picked up at their front doors, at no added cost.

Individuals who cannot remain home for the at-door hand-off can leave containers outside their front doors for pickup.

Last week, a majority of the Elk Grove City Council agreed to allow the at-door pickup as part of a newly modified franchise agreement with waste hauler Allied Waste Services.

Mayor Gary Davis and Councilwoman Sophia Scherman voted no, citing concerns about having containers left outside homes for pickup.

The program is intended to help residents, such as those with diabetes, meet the requirements of a new state law that took effect on Sept. 1.

The legislation makes it illegal to dispose of home-generated "sharps" in the trash or in recycling containers.

Cedar Kehoe, Elk Grove's integrated waste program manager, said the city is the first in the region to establish a comprehensive disposal program.

For a list of medical waste disposal facilities, visit the California Integrated Waste Management Board at www.ciwmb.ca.gov and search for "sharps."

Call The Bee's Loretta Kalb, (916) 478-2641

How to Start a Needle Disposal Program
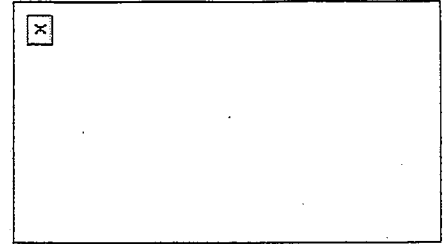
Guidelines for Establishing a Collection and Disposal Program

This year alone, nearly 9 million syringe users will administer 2 - 3 billion injections outside traditional health care facilities. Two-thirds of these "at-home" injectors are people with diabetes and patients receiving home health treatment (i.e. allergies, infertility, multiple sclerosis, even veterinary care). Many of these self injectors are unaware of safe disposal methods available to them and simply throw their used needles in the trash or flush them down the toilet, posing a risk of injury or potential infection from diseases such as Hepatitis B or C and HIV to anyone that encounters them.

With the growing practice of home health care and a predicted 165% increase in Americans diagnosed with diabetes over the next 50 years, this problem will only get worse if it is not addressed. Solutions are available that meet both individual and community needs. Below are six types of disposal programs that currently exist in the United States.

Drop-off collection sites: Some communities offer residents collections sites that accept used needles - many times for free. These collections sites may be at local hospitals, doctors' offices, health clinics, pharmacies, health departments, community organizations, police and fire departments and medical waste facilities.

Household hazardous waste services: Most communities have a disposal site already set up that accepts household hazardous waste items such as used oil, batteries, paint, etc.

Residential special waste pickup services: Some communities offer residents a special waste pickup service. When a resident has a full sharps container, these programs may ask residents to call for a pick up or offer residents a regular scheduled pickup.

Syringe Exchange Programs: Some communities offer programs that allow individuals to exchange used needles for new needles. To find out if your community offers a syringe exchange program call North American Syringe Exchange Network at (253) 272-4857 or online at www.nasen.org.

Mail-back programs: Individuals buy this program complete with sharps container and mail-back packaging. The individual fills the sharp container with used needles and mails it back in the shipping package that is provided by the manufacturer.

Home needle destruction devices: Several manufacturers offer products for sale that destroy needles at home by burning, melting or severing the needle - making it ok to throw the syringe in the garbage. Prices vary depending on the product.

The primary goal in implementing a safe community collection and disposal program is to minimize worker and public exposure to used sharps (syringes, needles and lancets) and to reduce the potential for injury or infection from accidental needle sticks.

Steps in Establishing a Community-based Sharps Collection and Disposal Program

Recognizing that local needs, resources and circumstances will vary, a safe sharps collection and disposal program should consider the following principles:

- Accessible. Safe sharps collection and disposal options should be easily accessible to all members of the community and conveniently available in terms of location, days and hours to ensure maximum utilization.

- Inclusive. Solutions should address the needs of all individuals in the community who use sharps.

- Affordable. Programs should be within reach of individuals at all income levels, including through reimbursement or subsidy when necessary.
- Confidential. Options should be available for Individuals who wish to dispose of sharps privately.

- Distinct. Disposal programs should consider directing sharps into a waste stream separate from the standard public waste stream.

- Safe. Programs should assure the safe collection and disposal of used sharps and comply with any pertinent federal, state or local requirements.

- Well-publicized. Information on disposal programs should be readily available through physicians, diabetes educators, nurses, pharmacists, substance abuse counselors, veterinarians and other health professionals who come into contact with those who use sharps.

- Supported by the community. To be effective, solutions should have broad-based community support.

Following are suggested steps for establishing a community sharps collection and disposal program. It is important to note that there is no single solution that will fit every situation, so flexibility is important.

Step One: Lay the Foundation

➢ Check the CDC Safe Community Disposal website for updated information on state needle disposal regulations www.cdc.gov/needledisposal.

➢ Check with local officials and community leaders to see if there are existing disposal guidelines or programs currently available in your community:
  - Local (city or county) public health officials
  - Local waste management departments
  - Local hospitals, clinics, doctors' offices and pharmacies
  - Local police and fire departments
  - Local diabetes educators through local hospitals
  - Community nonprofit organizations (Chapters from ADA, AADE)

  The Coalition website, www.safeneedledisposal.org, has contact information and hot line numbers for state health departments, as well as other helpful information and links to pertinent sites.

➢ Contact the Coalition for Safe Community Needle Disposal, at 800-643-1643 to see if they are

aware of others in your community who interested in establishing a sharps collection and disposal program.

Step Two: Build a Team

➤ Contact other interested parties to see what progress they have made and explore ways to collaborate on the project (e.g. public health officials, diabetes educators, HIV/HVC departments, waste officials, health industry [local chapters of AMA, AADE, ADA, ANA etc.], individuals)

➤ Identify a group leader and core team members.

Step Three: Clearly Define Your Needs and Priorities

Some factors that will help determine your needs and priorities are:
- Existing regulations and guidelines
- Size of community and affected population
- Urban, suburban or rural
- Demographics and characteristics of people who use sharps
- Existing programs
- Government and community support.

Step Four: Assess Your Options

➤ Examine available collection and disposal solutions to determine which best meets your community's needs.

➤ Possible solutions may include:

Community sharps collection and disposal sites. Used sharps are brought to a central collection site, either loose or placed in containers. At the site, sharps are received by facility personnel for removal to a storage area or placed by the individual into a sharps collection kiosk or other receptacle for future disposal. Collection or disposal sites may include:
- o Medical facilities (hospitals, health clinics)
- o Pharmacies
- o Municipal facilities (fire, police stations, waste disposal sites)
- o Collection drop box located in a public area
- o Human service agencies (senior citizens centers, churches, community-based organizations)

Availability: Currently hundreds of collection or disposal programs exist across the country, active states include Wisconsin, Rhode Island, Florida, California, Massachusetts, New York, Washington and 11 other states all have at least one existing program.

Costs: The individual cost can range from $0 to $10 which may or may not include a sharps container, but the community costs for implementation varies greatly depending on disposal costs and funding availabilities which include (grants, property-based taxes, waste tipping fees at landfills or transfer stations, donations, or city/county contributions).

The Houston Airport implemented 63 containers for about $2,000 in IAH restrooms and maintains the program for $225 - $270 per year. This program was implemented after custodial workers noticed an increase of used needles in bathroom garbage.

Contact: Thomas Bartlett, 281-230-3017, tombartlett@cityofhouston.net

The implementation costs for the Eureka Program of RI was $135,000 for all 39 sites which includes 50 kiosks, marketing campaign (posters, graphics, and brochures) sharps containers and disposal. The cost to maintain the program is approximately $750 per site per year. Funding was provided by Foundations, the state of Rhode Island, Stericycle, Rhode Island Resource Recovery and Diabetes Foundation of Rhode Island.
Contact: Cherie Kearns, Exec. Director, 401-725-7800 CherieK@dfri.org

Riverview Hospital in Wisconsin Rapids, Wisconsin offers a Sharp Smart Drop-off program to its community of approximately 25,000 people. Located in the main entrance of the hospital, individuals can drop off sharps disposed in household containers 24-hours a day. Funding for the project is provided by the Riverview Hospital Foundation. The implementation cost was $1600 for the cabinet that holds the 17-gallon sharps containers (individuals deposit their own container in a larger sharps container). The cost to maintain the program is approximately $2500 per year, which includes the hauling by Stericyle and the 17-gallon containers.
Melody Dearth - Director Environmental Services, 715-421-7443 deamel@rhahealthcare.org

Household Hazardous Waste Drop-off Sites. Used sharps are brought to a central collection site, either loose or placed in containers. Most communities have a disposal site or pick-up date already set up that accepts household hazardous waste items such as used oil, batteries, paint, etc. Contact your local waste department to see if your community household hazardous waste site accepts used needles.

City of San Bernardino. When the city of San Bernardino's hospital stopped accepting used sharps from community members, sanitation workers began to notice an increase in needle sightings - despite a city ordinance that prohibits disposing of used sharps in household trash. The city implemented a sharps disposal program in 1998 that allows sharps users to drop off sharps containers at the city's existing household hazardous waste (HHW) collection facilities without charge. The program has been successful, largely due to the fact that it is convenient and free. The California Integrated Waste Management Board funded the program for the first 2 years at an annual cost of $5,900. The city of San Bernardino now funds it at an annual cost of $6,000.

To publicize the program, the city offers a point-of-sale display to pharmacies and includes information about the program in the city newsletter. Linda Ceballos, 909 384-5549 ceballos_li@sbcity.org

Residential Special Waste Pick-up Service:
Home users place used sharps in a special "sharps" container and much like a recycling container; it is set outside for pick-up by special waste handlers.

Availability: Typically smaller communities offer this service to its residents. It's not known how many of these currently exist in the United States.

Cost: The community costs for implementation varies greatly depending on disposal and transportation costs. For example in some states there may be only one waste hauling company in the area - this causes the cost to rise tremendously.

Columbus, Georgia. The city of Columbus, Georgia, took a personal approach to its sharps disposal program after experiencing problems with sanitation workers suffering needle-stick injuries from

sharps discarded in household garbage. Residents can now collect their sharps in their own hard plastic container and call the city's waste management agency when their sharps container is full. A waste supervisor is then dispatched to their home to take the container for safe disposal.

By having waste collection supervisors, who are already in the field on their regular rounds, pick up sharps from residents, Columbus has provided a safe disposal option that costs the city virtually nothing. For more information, contact Contact Les Moore, 706-653-4161 Lesmoore@columbusga.org

Syringe exchange programs (SEPs). Syringe exchange programs offer individuals sterile syringes and needles in exchange for used ones. SEPs are believed to be an effective public health practice for reducing the number of HIV and HVB and HVC transmissions among injecting drug users.

Availability: There are 180 actual SEPS nationwide with 36 states and Washington DC, Puerto Rice and Indian Nations participating in SEPs. During 1998, SEPs operated at 534 sites averaging five sites per program (median: nine; range: 1--31). Sites included 202 health van stops, 59 shooting galleries, 56 sidewalk tables, 51 cars, 43 storefronts/indoor sites, 30 SEP workers on foot, 23 health clinics, and 70 other sites. Delivery of syringes and other risk-reduction supplies to residences or meeting spots was reported by 55 (50%) SEPs, and 94 (85%) allowed participants to exchange syringes for persons other than themselves (secondary exchange).

Costs: The combined operating budget of 105 SEPs in1998 was $8,567,662 (range: 0--$771,053; mean: $80,493; median: $38,000). A total of 51 SEPs in 15 states and Puerto Rico received public funding of $5,992,032. About one half of all programs receive funding from state and local governments and the other half is funded through grants and donations. The cost to the individual is always free. Contact North American Syringe Exchange Network at 253-272-4857 or visit www.nasen.org

Sharps container mailback service. Sharps containers packaged to meet U.S. Postal Service requirements are filled with used sharps and mailed to an approved facility for proper disposal. These containers are available commercially.

Availability: There currently are at least eight companies nationwide that offer a sharps mail back solution to patients.

The Sharps Compliance/BD/WM program is currently available nationwide through an 800 number and online. It is available nationwide in pharmacy chains. This program is a mail back container that holds approximately 100 used syringes or 300 pen needles. When the box is full it is shipped directly to an incineration plant in Texas where it is incinerated in a waste to energy plant. Contact Sharps Compliance at 877-927-8363 or visit www.sharpsinc.com

The Voyager is a portable container that severs the hull of the needle into the container, leaving the plunger to be disposed in the garbage. It holds approximately 100 needle tips and is available on websites and through private and chain pharmacies nationwide (CVS and Rite Aid). Contact 877-723-3633 or visit www.safemedical.com to find out more information.

Costs: The costs can vary from $15 to $50 depending on the manufacturer. Some containers will hold up to 300 needles others containers actually sever the needle tip into a container holding 100 of those. For a diabetes patient, this program is approximately $100 per year. For patients injecting less often it could be as little as $30 per year.

 Some municipalities are recognizing the flexibility benefits of mail-back programs and beginning to offer them to their residents. Restaurant chains, department stores, stadiums and school districts are also beginning to use mail-back programs as a viable disposal option for their collected sharps. Mail-

back programs can complement existing needle collection programs by offering mail back solutions for rural residents or homebound residents.

Alameda County, California is conducting a pilot program by distributing mail-back containers free of charge to medically underserved populations. The county's large size and diverse demographics have presented problems in adopting more traditional methods of safe sharps disposal, such as drop-off sites or residential collection. By contracting with a vendor for mail-back service, Alameda hopes to reach a greater percentage of its self-injecting population – if residents have a mailbox, they have access to the service. For more information, contact the Alameda County Sharps Coalition at 800-606-6606 or www.stopwaste.org.

At-Home Needle Disposal Products. Numerous "at-home" disposal products offer a variety of ways to destroy used needles. See the Coalition website for a vender list of disposal solution currently available www.safeneedledisposal.org.

Availability: The FDA has approved of some needle destruction devices. These small at-home units burn the needle down to a small ball. There also exists other devices that use chemicals to destroy needles; however, I don't believe those have been approved yet by the FDA. These devices may be available at chain and individual pharmacies nationwide, through a toll-free number or over the internet.

Also available are needle clipping devices. It is a device that clips the needles off into a container, much like the Voyager. Becton Dickinson, www.bd.com has the Safe Clip, which stores up to 1500 insulin tips. When complete this container should be dispose of through a mail back option or a community needle collection site.

Also, there are more than 15 manufacturers of sharps containers that are available on the market to individuals. Many people deposit their used needles in these containers and then ask their doctors or local hospitals to accept their used containers. This approach depends on the good-nature of hospitals and physicians.

Cost: Needle-destruction devices vary from $89 - $180. Most last between three and five years. Needle clippers are as little as $5 and as much as $10. Call 877-797-4277 for more information on the Disintegrator.

Sharps containers may cost as little as $1 to $25, however, finding a charitable physician or hospital to accept full sharps containers costs time only.

Step Five: Select the Best Option

➢ Match program options with your community's needs and available resources to find the best fit. (Until your program is in place and fully operational, continue to follow local regulations or EPA guidelines for sharps disposal.)

Step Six: Implementation

➢ Work with other members of your community and local/state officials to put the program in place.

➢ Work with state and local officials, healthcare workers and community leaders to publicize the program and to encourage creation of more programs that will remove sharps from the public

waste stream.

➤ Consult the Coalition for additional guidance at 800-643-1643.

Step Seven: Monitoring and Evaluation
➤ Determine how you will evaluate your program. Seek assistance from someone experienced in evaluation or contact the Coalition at 800-643-1643 for evaluation information.

➤ Develop measurement criteria and evaluation milestones. Examples of measurement criteria might include:
  o Are people participating in the program, i.e., how many used needles are being turned in or how many pounds of sharps have been collected?
  o Does the program fulfill the abovementioned principles for effective sharps disposal?
  o Is the community supporting the program?
  o Does the program serve the population for which you created it?
  o Could the program be expanded to serve additional groups?

➤ Evaluate your program at pre-determined points based on your measurement criteria.

➤ If necessary, make adjustments.

➤ Contact the Coalition for Safe Community Needle Disposal to keep us apprised of the status of your program.

For more information, please contact the coalition at 713-980-3120 (800-643-1643) or visit our Web site at www.safeneedledisposal.org.

Typical Challenges Facing Safe Collection and Disposal Programs

Some or all of the following challenges may be encountered in working to establish an effective sharps collection and disposal program:

- Funding. Getting the funding necessary to establish a program can be a constant challenge. Possible sources include: federal, state and local government grants; charitable foundations (Hospital and corporate foundations); local nonprofit organizations (United Way, churches, etc.) that support public safety programs; and corporate contributions. Organizations and individuals who are unable to make financial contributions might be willing to donate in-kind support - product, services or volunteer time.

- Community acceptance. The general public is unaware of the range of reasons that individuals use sharps outside health care facilities. It can therefore be difficult to attract community support to such a program. Education is critical to raise public awareness that improper sharps disposal poses a potential health risk for everyone in the community and that an effective solution is in everyone's interest.

- Government support. Federal government funding for collection and disposal programs is minimal, but state and local governments are permitted to allocate their funds to these programs.

- Need for behavioral change. Individuals who use sharps at home may be unaware of the

danger their discarded sharps pose to their communities. Making individuals aware of the safety threat to workers and the general public from improper disposal of used sharps will help establish a foundation for changed behavior. Educating these individuals and helping them identify and adopt other options as they become available is critical for the long-term success of a community safe collection and disposal program.

- Finding the right fit. There is no one solution that can easily work in every community. Removing used sharps from the community may require trial and error before the right program or programs are identified.

San Luis Obispo County
Integrated Waste Management Authority
ORDINANCE NO. 2008-2

AN ORDINANCE ESTABLISHING A
SHARPS (HYPODERMIC NEEDLES) WASTE
MANAGEMENT PROGRAM

The Board of Directors of the San Luis Obispo County Integrated Waste Management Authority ordains as follows:

Section 1. General Provisions

The San Luis Obispo County Integrated Waste Management Authority (IWMA) finds and declares all of the following:

(a) The purpose of this Ordinance is to have the IWMA, a joint powers agency established pursuant to Government Code Section 6500 and empowered by its member jurisdictions to exercise the members' common powers to achieve the mandates imposed by the Integrated Waste Management Act of 1989 (AB 939) on a regional basis, enact a comprehensive and innovative system for the proper and legal management of home-generated sharps waste (hypodermic needles waste) in San Luis Obispo County in accordance with Section 118286 of the Health and Safety Code.

(b) The purpose of this Ordinance is to enact a law that establishes a program that is convenient for consumers and the public to return and ensure the safe and environmentally sound disposal of home-generated sharps waste, and to provide a "no-cost" system for consumers for the return of home-generated sharps waste.

(c) The purpose of this Ordinance is to assure that the costs associated with the handling and disposal of home-generated sharps waste are the responsibility of the producers and retailers of home-generated sharps waste, and not local governments or their service providers, state or local government, or taxpayers.

(d) The purpose of this Ordinance is to reduce the likelihood of the illegal disposal of home-generated sharps waste, and it is the intent of this Ordinance to ensure that all costs associated with the proper management of home-generated sharps waste are internalized by the producers and consumers of home-generated sharps waste at or before the point of purchase, and not at the point of discard.

(e) The purpose of this Ordinance is to assure that manufacturers and retailers of sharps, while working to achieve the goals and objectives of this Ordinance, should have the flexibility to partner with each other, and with those private and nonprofit business enterprises that currently

provide collection and processing services, to develop and promote a safe and effective home-generated sharps waste management system.

(f) The purpose of this Ordinance is to provide for the safe and convenient collection and disposal of 100 percent of the home-generated sharps waste discarded in the IWMA Region at no cost to the consumer and to comply with the requirements pursuant to State Health and Safety Code prohibiting the disposal of home generated sharps waste in landfills as of September 1, 2008.

Section 2. Definitions

For the purposes of this Ordinance, the following terms have the following meanings, unless the context clearly requires otherwise:

(a) "Consumer" means an individual who has purchased sharps for personal use.

(b) "Home-generated sharps waste" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household.

(c) "IWMA Region" means the geographic area that includes the unincorporated area of San Luis Obispo County, California and the seven incorporated cities within San Luis Obispo County.

(d) "Retailer" means any entity, including but not limited to, a person or business, of whatever form of organization, which sells to the general public sharps in the IWMA Region to a consumer, including a manufacturer of sharps who sells sharps directly to a consumer.

(e) "Distributor" means a person who sells sharps to a retailer.

(f) "Sharps" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications.

Section 3. Sharps management

(a) By September 1, 2008, every retailer of sharps sold in this IWMA Region shall establish within the retail outlet a system for the acceptance and collection of home-generated sharps waste for proper disposal.

(b) Each system established by a retailer for the acceptance and collection of home-generated sharps waste during the retailer's normal hours of operation, for proper disposal shall, at a minimum, include all of the following elements:

(1) A convenient location within the retail establishment for the "take-back" from the consumer of home-generated sharps waste at no cost to that consumer.

(2) Appropriate signage, prominently displayed within 5 feet of any entrance to the retail establishment and easily visible to the consumer, indicating that the retail establishment accepts

and collects home-generated sharps waste from consumers.

(3) An appropriate receptacle or receptacles for the collection of home-generated sharps waste within the retail establishment.

(c) A retailer who is required to accept home-generated sharps waste shall at a minimum provide the following take back services:

(1) The take-back from the consumer of home-generated sharps waste that the retailer sold or previously sold to the consumer, at no cost to that consumer. In that event, the retailer may require proof of purchase of the prior sales. The retailer shall only be required to accept home-generated sharps waste in an amount not to exceed the amount previously sold to the consumer.

(2) The take-back of home-generated sharps waste from a consumer purchasing sharps from the retailer, at no cost to the consumer. In that event, the retailer shall only be required to accept home-generated sharps waste in an amount not to exceed the amount being purchased.

(3) The take-back from the consumer of home-generated sharps waste that the retailer did not sell or previously sell to the consumer, at no cost to that consumer. The retailer shall only be required to accept home-generated sharps waste in an amount not to exceed a 2 quart size sharps containers per week per consumer from any consumer who resides in the IWMA Region.

Section 4. Enforcement

(a) The IWMA may enforce the provisions of this Ordinance through a civil action for civil penalties in the amounts established herein, and any other civil remedy, including prohibitory and mandatory injunctive relief, filed in the Superior Court for the County of San Luis Obispo to compel and enforce the provisions herein against any retailer within San Luis Obispo County who sells sharps in violation of this Ordinance. In addition to any relief available to IWMA to enforce this Ordinance, the IWMA shall also be entitled to recover its reasonable attorneys' fees and costs incurred in enforcing this Ordinance.

(b) For any violation of this Ordinance, the IWMA may sue to recover civil penalties in the amount of $1,000.00 per day for every day on which a violation exists. For purposes of calculating the civil penalties to be established hereunder, each day on which the retailer fails to comply with the requirements of this Ordinance, after having received a written notice of violation issued by the IWMA, shall constitute a separate offense.

(c) In addition to the civil relief available to the IWMA set forth above, any violation of this Ordinance shall also constitute a misdemeanor punishable under the laws of the State of California. The District Attorney, the County Counsel, or any City Attorney shall be authorized to enforce the provisions of this Ordinance within their respective jurisdictions. In the event of such criminal enforcement, the following criminal penalties apply to violations of this Ordinance:

(1) Violation as Misdemeanor. Violations of the provisions of this Ordinance or failure to comply with any of its requirements shall constitute a misdemeanor.

(2) The San Luis Obispo County Sheriff's Department and/or any other police department or law enforcement agencies located within the IWMA's jurisdiction may issue a Notice to

Appear Citation for any misdemeanor pursuant to California Penal Code Section 853.6 for any violation of this Ordinance.

(3) Penalty for Misdemeanor. Any retailer found to be in violation of any provision of this Ordinance, or who fails to comply with any of its requirements, shall upon conviction thereof be punished by imprisonment in the county jail for not more than six months, or be fined not more than one thousand dollars ($1,000.00), or by both. Each day such violation continues shall be considered a separate offense.

(d) To the extent that the County of San Luis Obispo, the incorporated cities, and the districts within said County have adopted code enforcement ordinances applicable to their jurisdictions, this Ordinance shall be enforceable by said governmental entities under said ordinances as land-use or code-enforcement violations consistent with said ordinances.

Section 5.   CEQA Findings

The Board of Directors of the IWMA finds that this Ordinance is exempt from the California Environmental Quality Act pursuant to CEQA Guidelines § 15061(b)(3) because "it can be seen with certainty that there is no possibility that the activity in question may have a significant effect on the environment." In addition, the Ordinance is subject to a Class 1 categorical exemption pursuant to CEQA Guidelines § 15301 in that the activities mandated by the ordinance will occur at existing retail establishments and, therefore, consist "of the operation, repair, maintenance, permitting, leasing, licensing or minor alteration of existing public or private structures, facilities, mechanical equipment, or topographical features, involving negligible or no expansion of use beyond that existing at the time of the lead agency's determination.... The key consideration is whether the project involves negligible or no expansion of an existing use." The IWMA Manager is directed to prepare and file an appropriate notice of exemption.

Section 6.   Severance Clause

If any section, subsection, sentence, clause or phrase of this Ordinance is for any reason held to be unconstitutional, ineffective or in any manner in conflict with the laws of the United States, or the State of California, such decision shall not affect the validity of the remaining portions of this Ordinance. The Governing Board of the IWMA hereby declares that it would have passed this Ordinance and each section, subsection, sentence, clause and phrase thereof, irrespective of the fact that any one or more sections, subsection, sentence, clause or phrase be declared unconstitutional, ineffective, or in any manner in conflict with the laws of the United States or the State of California.

Section 7.   Effect of Headings in Ordinance.

Title, division, part, chapter, article, and section headings contained herein do not in any manner

affect the scope, meaning, or intent of the provisions of this Ordinance.

This Ordinance was introduced and the title thereof read at the regular meeting of the IWMA Board of Directors on March 12, 2008 and further reading was waived by a majority vote of those Directors present.
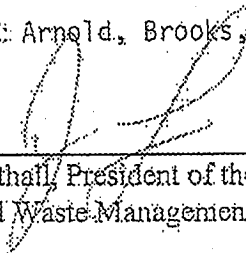
This Ordinance shall take effect and be in full force on and after thirty (30) days from the date of its passage, and before the expiration of fifteen (15) days from the date of its passage it shall be published once with the names of the members of the Board of Directors voting for and against the same; said publication to be made in a newspaper of general circulation published in the County of San Luis Obispo.

On a motion by Director ___Gibson___, seconded by Director ___Achadjian___, the foregoing Ordinance was passed and adopted by the Board of Directors of the San Luis Obispo County Integrated Waste Authority, this (insert date), by the following vote:

AYES: Achadjian, Ashton, Beraud, Ehring, Gibson, Hamon, Mulholland, Patterson and Lenthall
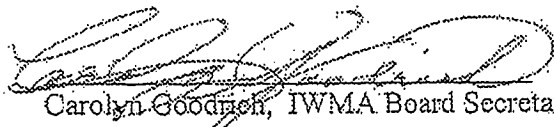
NOES: None

ABSENT: Arnold, Brooks, DeMeritt, and Ovitt
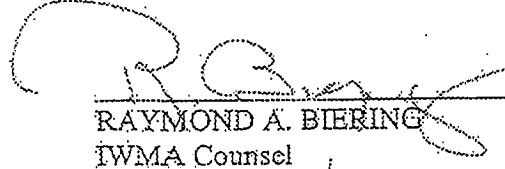
_____
Jerry Lenthall, President of the San Luis Obispo County
Integrated Waste Management Authority

ATTEST:

_____
Carolyn Goodrich, IWMA Board Secretary

ORDINANCE CODE PROVISION APPROVED
AS TO FORM AND CODIFICATION:

_____
RAYMOND A. BIERING
IWMA Counsel

Date: 3/17/08

3. Locate a medical waste hauler by going to the California Department of Public Health website at **http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf** to dispose of home-generated sharps waste.

4. Let self-injectors know about your pharmacy's sharps collection service.

5. The CIWMB will place your business on CIWMB's searchable web page, so the public can find a location to dispose of sharps.
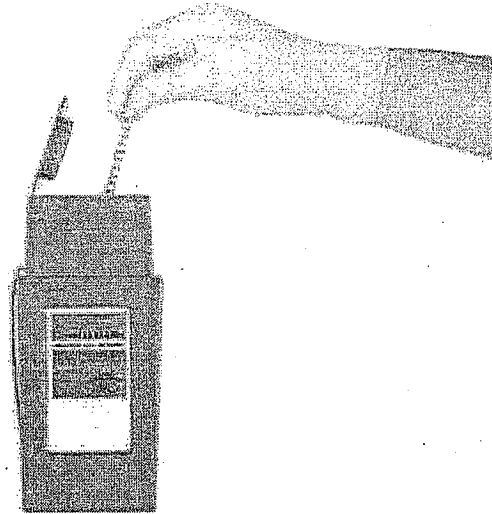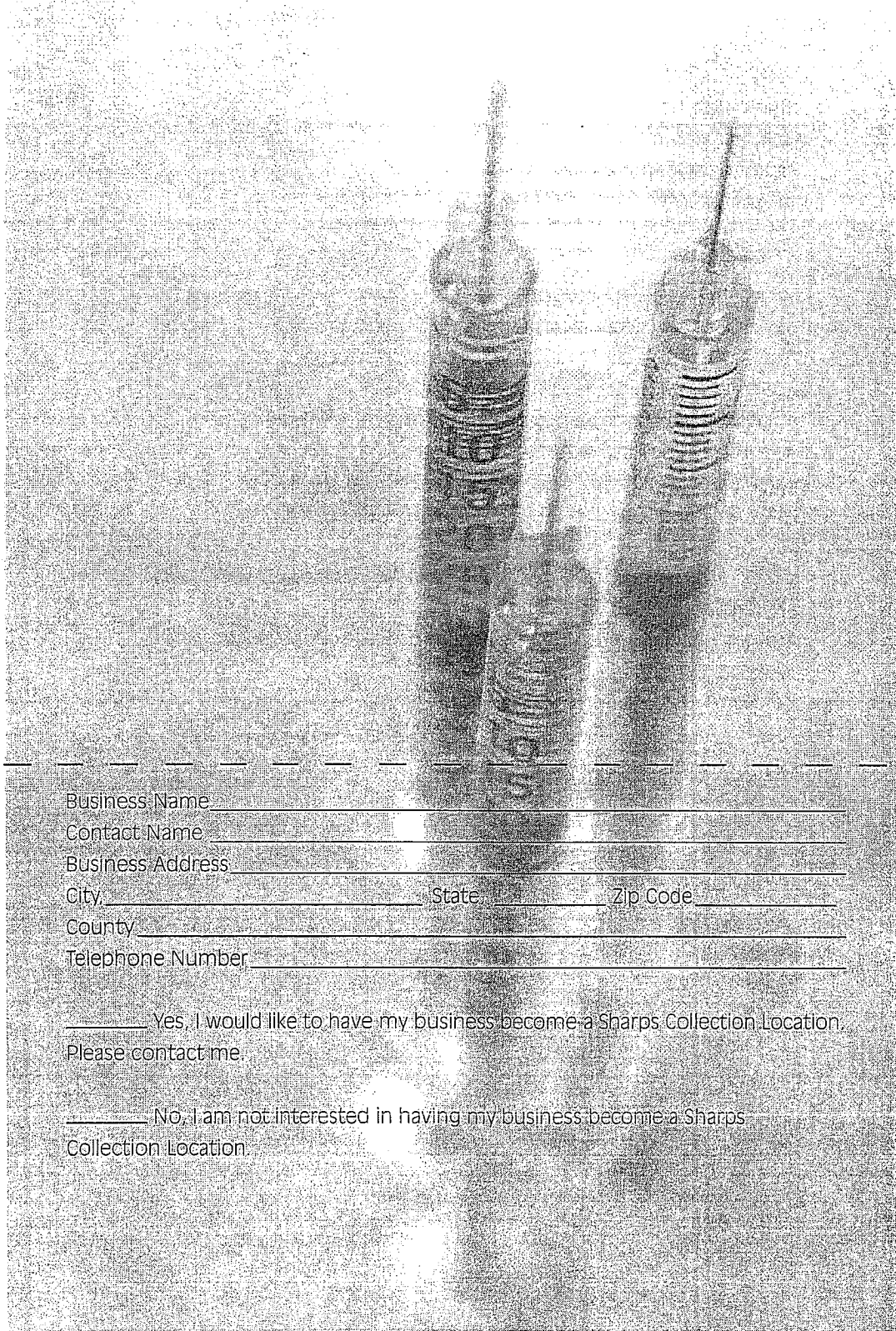
Searchable List of Sharps Collection Locations by County, Located at:

http://www.ciwmb.ca.gov/HHW/Healthcare/Collection/or call 1-800-CLEANUP

Business Name _____

Contact Name _____

Business Address _____

City _____ State _____ Zip Code _____

County _____

Telephone Number _____

_____ Yes, I would like to have my business become a Sharps Collection Location. Please contact me.

_____ No, I am not interested in having my business become a Sharps Collection Location.

By Becoming A Collection Location for Disposal of Home-Generated Sharps, Your Pharmacy Could:

Increase your customer base:

- Gain free advertising from the posting of your facility on the CIWMB Sharps Waste Web Page.

- Help customers meet the new sharps requirements; and increase the number of diabetics purchasing syringes and insulin.

Effective September 1, 2008 - State law makes it illegal to dispose of sharps - (hypodermic needles, pen needles, intravenous needles, and lancets) in the trash or recycling containers.

Effective September 1, 2008 - Sharps waste can only be transported in approved sharps containers and can no longer be disposed in coffee cans, detergent bottles, soda bottles, milk jugs, or in the trash.

Effective September 1, 2008 - Sharps can only be managed at a household hazardous waste facility, a home-generated sharps collection location (which may be a pharmacy or a medical waste generator's facility), a hospital, clinic, or through a mail-back program.

How to Become a Sharps Collection Location

1. Complete the post card and return to the California Department of Public Health.

2. You will be contacted by the Local Enforcement Agency (LEA) to complete some additional information and receive **information** on storage and handling requirements.

Californians
Need Your
Help!

Become a
Sharps
Collection
Location

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: December 2, 2008

To: Enforcement Committee

Subject: E-Prescribing Update

On November 20, 2008, the Board of Pharmacy hosted an e-prescribing forum in conjunction with the Department of Consumer Affairs' Professionals Achieving Consumer Trust Summit. Other healing arts boards whose licensees prescribe drugs attended this forum as did our stakeholders and public interest groups. The Dental Board and Medical Board joined us as partners.

The board hosted this forum to provide information about e-prescribing in hopes of fostering its implementation in California.

A number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing for prescription medicine. A principal reason is that statistics indicate that medication errors cost the health care system $77 billion and cause 7,000 deaths annually. A number of these errors could be prevented by full implementation of e-prescribing. Other savings have been projected from redirected time currently spend by prescribers and pharmacies in verifying and switching prescription orders.

By the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. Since then, various provisions have been added or amended to keep law supportive of allowing electronic prescriptions. A current deterrent is that controlled substances cannot be e-prescribed

At the board's November 20 forum, the agenda involved a review of California's laws authorizing e-prescribing, a presentation by a software company that provides the infrastructure to perform e-prescribing, and presentations by several large entities that are currently using e-prescribing to describe their experiences – what works and lessons learned. PowerPoint presentations made during this meeting are available on line from the board's Web site:
http://www.pharmacy.ca.gov/about/presentations_on_eprescribing.shtml

Meanwhile, the California HealthCare Foundation also sponsored a forum on e-prescribing on November 20 in San Francisco. The agenda from this meeting and background materials distributed at this forum are attached.

Generally, the two forums were comprised of similar presentations. Moreover, the two forums provided opportunities for strong policy initiatives to move forward encouraging e-prescribing in California. Legislation may be one outcome of these efforts.

The board's Executive Officer Herold is a member of the group formed by the California HealthCare Foundation to work towards achieving e-prescribing in California by 2012, which was one goal in Governor Schwarzenegger's 2008 health reform package.

The committee should plan to discuss what if any future action the board needs to take in this area.

CALIFORNIA
HEALTHCARE
FOUNDATION

California HealthCare Foundation
E-Prescribing Convening
Thursday, November 20th
10:00 am – 3:00 pm
Bentley Reserve Building
301 Battery St.
San Francisco, CA 94111
ph: 415.728.6729

Agenda

Session	Time
Welcome and Introductions • Mark Smith, M.D., President & CEO, California HealthCare Foundation • Joe Munso, Undersecretary, California Health and Human Services Agency	10:00 – 10:30 am
Early Adopter – Health Alliance Plan, Michigan • Matthew Walsh, Associate Vice President, Purchasing Initiatives, Health Alliance Plan	10:30 – 11:00 am
Statewide E-Prescribing Plan *Introduction of a statewide plan that aims to achieve eRx as the standard of care in California by 2012.* • Jonah Frohlich, Senior Program Officer, California HealthCare Foundation **Facilitated Panel Discussion** • Moderator: Chris Rauber, Health Care Reporter, San Francisco Business Times • Health Plan: Charles Kennedy, M.D., Vice President, Health Information Technology, WellPoint • Purchaser: Ellen Badley, Division Chief, Health Benefits Branch, CalPERS • Pharmacy: Scott Barclay, General Manager, CVS Caremark • Provider: Steve Tremain, M.D., Director of System Redesign, Contra Costa Regional Medical Center	11:00 – 12:15 pm
Lunch	12:15 – 1:00 pm Upstairs Lounge
Breakout Session 1 (Please attend session assigned at registration)	1:00 – 1:45 pm
Provider Adoption *Session will review proposed provider adoption strategies and suggest strategies for prioritization. Session will also address opportunities to align provider incentives and explore how best to ensure optimal vendor functionality and support.* Moderators • Bill Spooner, Senior Vice President & CIO, SHARP HealthCare • Sandy Newman, Director of Health Policy, California Academy of Physicians	Room: Apollo Color: Red
Consumer Confidence & Purchaser Demand *Session will explore current efforts to engage purchasers in e-prescribing and how purchasers may consider using contracting as a motivator to engage plans and their provider networks in e-prescribing. Session will also consider consumer confidence in e-prescribing and identify areas, such as consent, and other privacy concerns that must be addressed.* Moderators • Jim Dempsey, Vice President Public Policy, Center for Democracy and Technology • Patrick Robinson, Pharmaceutical Consultant, CalPERS	Room: Cordova Color: Blue

Pharmacy Connectivity *Session will explore current gaps in pharmacy connectivity and mechanisms to address such gaps, especially among independent pharmacies. Session will address support necessary to engage pharmacies in e-prescribing and sustain participation in an e-prescribing initiative.* Moderators • Doug Hillblom, Representative, California Pharmacists Association • Matt Lowe, Vice President, Retail Marketing, McKesson	Room: Ninantic Color: Green
Dashboard Test Drive *Join a live focus group to review the E-Prescribing Dashboard currently in development and provide feedback on the design elements, usability, and data requirements for the site.* Moderator • Libby Sagara, Manager, Manatt Health Solutions	Room: Euphemia Color: Purple
Breakout Session 2 (Please attend session assigned at registration)	1:45 – 2:30 pm
Consortium Formation *Session will provide an overview of consortium goals, principles, and objectives and pose, discuss, and evaluate options for consortium governance, funding, and administration.* Moderators • Ellen Badley, Division Chief, Health Benefits Branch, CalPERS • Tom Groom, Senior Vice President, Business Development, SureScripts-RxHub	Room: Apollo Color: Red
Financing and ROI *Session will explore how two health plans currently calculate e-prescribing savings and discuss how applicable these experiences are to others in the state. Session will also define the parameters to be covered in a statewide ROI meta analysis.* Moderators • Charles Kennedy, M.D., Vice President, Clinical Informatics WellPoint • Matthew Walsh, Associate Vice President, Purchasing Initiatives, Health Alliance Plan	Room: Ninantic Color: Green
Regulatory and Legislative Landscape *Session will explore e-prescribing's federal and state legal landscape including state policy activity. Participants will discuss a policy framework to identify obstacles to implementation and areas for further guidance.* Moderators: • Ann Boynton, Managing Director, Manatt Health Solutions • Frank LaPallo, Partner, Manatt, Phelps and Phillips, LLP	Room: Cordova Color: Blue
Dashboard Test Drive *Join a live focus group to review the E-Prescribing Dashboard currently in development and provide feedback on the design elements, usability, and data requirements for the site.* Moderator • Libby Sagara, Manager, Manatt Health Solutions	Room: Euphemia Color: Purple
Wrap Up CMS Region IX Update • David Sayen, Regional Administrator, CMS Dashboard Preview Next Steps	2:30 – 3:00 pm Upstairs Lounge (Lunch location)

Endorsement Statement
California HealthCare Foundation
Statewide E-Prescribing Planning Advisory Group

The California HealthCare Foundation Statewide E-Prescribing Planning Advisory Group, a collaborative of health plans, provider organizations, pharmacies, employers/purchasers, PBMs, government, and consumer/patient organizations, aims to achieve e-prescribing as the standard of care by 2012.

As indicated by the signature of _____

                                                                                     (Name)

representing_____,

                                                                     (Organization)

we hereby endorse the following:

- o The formation of the California E-Prescribing Consortium
- o The tracking of e-prescribing utilization and connectivity via a publicly available dashboard
- o The guiding principles set forth by the Consortium
- o The business objectives and policy guidance set forth by the Consortium

By endorsing said standard and rules of exchange,

_____

                                                                     (Organization)

will support the adoption and utilization of e-prescribing in California.

Signed by: _____, on Date: _____

_____

(Name)

_____

(Title)

_____

(Organization)

Getting Connected:
The Outlook for Electronic Prescribing in California

Introduction

Over the past three years, electronic prescribing (e-prescribing) has gained considerable attention from policymakers at both the state and national level. Successful pilot projects in Florida, Massachusetts, southeast Michigan, and elsewhere have demonstrated the technology's value to providers, health plans, pharmacies, and patients in improving patient safety, producing efficiency, and reducing out-of-pocket expenses. However, despite the considerable benefits of e-prescribing, it has yet to be widely adopted. Persistent barriers remain, including the costs involved in implementing the technology at provider practices, clinics, and pharmacies; legal restrictions that prevent electronic prescribing of controlled substances; and fees associated with using e-prescribing networks.

This year, Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA), a package that mandates e-prescribing incentive payments starting in 2009 and imposes penalties for those who do not adopt e-prescribing by 2012. The introduction of such federal incentives (which often prompt private payers to follow suit) has sharpened the focus on e-prescribing. This issue brief examines the technology's progress in California and describes how greater alignment of health care stakeholders can stimulate adoption.

Accelerating e-prescribing adoption in California will require a coordinated effort from all stakeholders. This could include advocacy to model state policy after federal legislation and education to describe benefits that generate support for e-prescribing programs. Collaboration among payers to align incentives (and penalties) to support e-prescribing by contracted providers and similar programs for pharmacies should be considered. Finally, providers and pharmacies may need tools and technical assistance to support e-prescribing.

Background

Paper-based prescribing processes are inefficient; relying on phone calls and faxes between pharmacies and physician offices can account for up to 25 percent of pharmacists' time and 20 percent of the workload for the staff in physician offices.[1] In California, the administrative cost associated with dispensing drugs for a Medicaid beneficiary is $13.18 per prescription—the highest in the nation.[2]

Paper-based prescribing is also unsafe. The Institute of Medicine estimates that, nationwide, as many as 7,000 people die each year from medication errors. Most of these deaths could be avoided if providers had access to accurate and

Definition of E-Prescribing

E-prescribing is the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.

Centers for Medicare and Medicaid Services. 42 C.F.R. Part 423.

complete information about their patients and could avoid writing their prescription orders by hand.[3]

Americans increasingly rely on prescription medicines to manage their health. Fifty-one percent of children and adults in the United States are taking one or more prescription drugs for a chronic condition, and one in four seniors are taking five or more medicines regularly.[4] Given the increased administrative burden imposed by the growing demand for drug therapies, e-prescribing has the potential to help reduce costs while improving patient safety and the quality of care.

The State of E-Prescribing in California

In 2007, California's retail pharmacies filled more than 268 million prescriptions. Of these transactions, an estimated 2.4 million were sent electronically between physician practices and pharmacies.[5] While this is a significant improvement from the 311,097 recorded in 2005, it represents only 1.2 percent of the total prescriptions written in California each year.[6] (These figures do not include closed systems such as Kaiser Permanente or the Veterans Administration; prescriptions generated electronically and printed at the point of care; or those sent to pharmacies via fax.)

Physicians who want to switch to e-prescribing face a myriad of barriers, including technology costs, productivity and workflow disruption, and lack of technical support. Successful initiatives are characterized by providers who:

- Have realistic expectations for and understanding of e-prescribing;

- Effectively integrate e-prescribing technology into their clinical workflow; and

- Receive sufficient technical support, either from on-site staff or a helpdesk.[7]

Connecting Providers and Payers

E-prescribing is most valuable to providers when it gives them complete information about their patients. The majority of such information, including pharmacy history, insurance eligibility, and formulary information is delivered to providers through RxHub, a network of three major pharmacy benefit managers who formed a joint venture in 2001 to enable electronic data exchange. Through this network, providers can retrieve a patient's eligibility, medication history, and formulary information from health plans that make it available. According to one national survey, such transparency may account for as much as 70 percent of the value and patient safety benefits attributable to e-prescribing.[8] In California, however, it is estimated that less than 30 percent of payers are making this information available through RxHub.[9]

Connecting Providers and Pharmacies

Retail pharmacies and physicians transmit prescription information electronically using the SureScripts network. SureScripts was founded in 2001 by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA). In 2008, SureScripts reported that 70 percent of California's 6,557 retail pharmacies were able to connect with the Pharmacy Health Information Exchange (PHIE) network, yet only 53 percent use it regularly. On the provider side of the transaction, the inability to connect to a particular pharmacy through the PHIE means physicians must revert to using handwritten, printed, or faxed prescriptions. The interdependency between providers and pharmacies highlights the importance of the local pharmacy participation and the need to promote pharmacy readiness alongside provider adoption. Encouraging e-prescribing will require that both pharmacies and providers receive adequate technical assistance and support.

E-Prescribing Tools and Standards

Technology vendors offer both stand-alone applications and e-prescribing tools embedded in electronic health

record systems. Over 130 technology vendors are able to route prescriptions to retail pharmacies using the PHIE and over 50 vendors have access via RxHub.[10]

E-prescribing also requires the use of standards to exchange data. A successful 2006 Centers for Medicare and Medicaid Services (CMS) pilot project resulted in a final CMS rule requiring Medicare providers to follow the approved standards beginning in April 2009. The rule details key components of the e-prescribing standard, including:

- Formulary and drug benefit plan information;

- Medication history;

- Fill-status notification; and

- Required use of the National Provider Identifier system mandated under the Health Insurance Portability and Accountability Act of 1996.

Other medication standards, terminology, and real-time prior-authorization standards are being refined.

Policymaking and E-Prescribing

California

Citing the overwhelming number of patient deaths and costs due to medical errors and adverse drug interactions, Governor Arnold Schwarzenegger proposed universal e-prescribing by 2010 as a key component to achieving affordable, safe, and accessible health care for all Californians.[11]

California's legislative leadership has also highlighted the need to support greater adoption of e-prescribing. In California, the Medication Errors Panel, authorized through a resolution introduced by Senator Jackie Speier, recommended that the state improve prescription transcription and transmission processes by supporting the adoption of e-prescribing.[12,13]

Federal Support

A number of federal agencies, most notably CMS and the Drug Enforcement Administration (DEA), are taking steps to support e-prescribing, either through modifications to existing programs or regulations.

Medicare Package

In July 2008, Congress passed the Medicare Improvements for Patients and Providers Act, which includes e-prescribing incentives and penalties that combine to impose a carrot-and-stick approach to promoting broader adoption. The law provides a reimbursement bonus of 2 percent for providers who have switched to e-prescribing by 2009, an amount that shrinks to 1 percent in 2011 and 0.5 percent in 2013. Providers who fail to make use of the technology will begin to see their payments reduced by 1 percent in 2012, 1.5 percent in 2013, and 2 percent in 2014 and beyond.

The CMS planning efforts around the rule's implementation include regional telephone briefings and a national conference to explain the new e-prescribing incentives for Medicare and address potential obstacles.

Medicare Part D

The most immediate change likely to spur e-prescribing adoption is the Medicare Part D requirement that prescription drug plans accept such transactions. The federal mandate applies to patients and prescriptions covered under Medicare Part D and will become effective in April 2009. The data sharing that must be supported between providers and pharmacies include:

- Patients' medication histories;

- Health plan formularies and benefits information, including the availability of generic drugs; and

- Prescription fill-status notification, enabling pharmacies to alert providers when patients' prescriptions are dispensed.[14]

In anticipation of these requirements, payers are upgrading their systems to accept and support electronic transactions before the April 2009 deadline. Because payers' reimbursement structures tend to follow CMS's lead, it is expected that those participating in Medicare Part D will likely extend their electronic prescribing capabilities to other lines of business.

DEA-Proposed Rule Change

The Drug Enforcement Administration prohibits controlled substances (Schedule II-V drugs) from being prescribed electronically. This presents a significant hurdle for e-prescribing providers who are forced to maintain parallel workflows—an electronic one for non-controlled substances and a paper process for controlled drugs. A proposed rule from the DEA would impose tight controls for e-prescribing of controlled substances with several restrictions. In anticipation of the DEA's rule change, the California Legislature has enacted a statute stating that electronic prescriptions need not be replicated on paper.[15] However, until the DEA modifies its Schedule II-V standards, California pharmacies must continue to create paper copies of these prescriptions.

Regional Pilot Programs

While state and national leaders are focused on developing policies and financial incentives to encourage adoption of e-prescribing, privately funded initiatives are fostering their own efforts that may provide insights into best practices, as well as useful lessons. Together, these programs have the potential to demonstrate e-prescribing's value to providers throughout the spectrum of care settings, including rural and safety-net clinics and private practices.

L.A. Care Health Plan

The L.A. Care Health Plan is the largest public health plan in America, with 10,000 physicians serving 780,000 members from low-income and vulnerable populations. L.A. Care is providing a stand-alone e-prescribing system and training to 150 high-volume prescribers. The pilot

project includes an incentive program, as well as baseline and follow-up surveys to measure physician satisfaction. Benefits identified to date include time savings to providers and staff from electronic renewals and the elimination of illegible handwriting; fewer adverse drug interactions; and greater use of generic medications.

Regional Successes Across the Country

Florida: *ePrescribe Florida* is a collaborative effort driven by Florida health plans. To date, the collaborative has released a registered vendor list tied to the state's existing pay-for-performance program and developed a Web "clearinghouse" designed to foster the adoption of e-prescribing throughout the state. The clearinghouse can be found at www.fhin.net/eprescribe/Index.shtml.

Massachusetts: *Massachusetts Health Data Consortium* (a.k.a. MA-SHARE) members initiated a project in 2006 to provide e-prescribing capability to the state's two largest academic medical centers. The resulting RxGateway product is intended to be a springboard for larger clinical data exchange. The participating payers harmonized their incentives to encourage physician adoption.

Michigan: The *Southeast Michigan E-Prescribing Initiative (SEMI)*, initiated by the region's major automotive employers, used direct incentives to encourage physicians to adopt e-prescribing technology. Active in seven counties, SEMI is approaching 3,000 prescribers and generating 4,000 prescriptions per month.

Mississippi: The state Medicaid program has reported over $14 million in savings following the implementation of an e-prescribing and clinical decision-support system for over 200 providers. Providers are able to access 100-day prescription histories and other tools for Medicaid patients via handhelds and a mobile-phone network.

Northern Sierra Rural Health Network

The Northern Sierra Rural Health Network (NSRHN) is implementing e-prescribing through a stand-alone application, meaning one that is not integrated with an electronic health record system. The pilot program,

funded by the Blue Shield of California Foundation and the California HealthCare Foundation, includes rural hospitals, clinics, providers, and pharmacies, as well as the SureScripts-RxHub network, and the California Department of Health Care Services (DHCS). DHCS is sharing eligibility, formulary information, and medication histories to participating NSRHN pilot sites. The project will bring the data to six clinics and two hospitals over 12 months.

California Health Care Safety Net Institute

The California Health Care Safety Net Institute (SNI) promotes quality improvement and innovation among the members of the California Association of Public Hospitals and Health Systems (CAPH). SNI designed a program to promote safe and efficient e-prescribing practices for the underserved and uninsured in California's public hospital clinics. SNI has engaged four CAPH member organizations, their outpatient pharmacies, and two outpatient clinics per site in a pilot program to extend e-prescribing technology to ambulatory care providers. As the sites go live with their selected e-prescribing tools throughout 2009, CAPH hopes that the program will help pave the way for broader use among their remaining member public hospitals and health systems.

A Framework for E-Prescribing Adoption in California

The California HealthCare Foundation recently conducted a California market assessment in which more than 30 health care industry leaders were interviewed about their respective roles in advancing e-prescribing. Stakeholders discussed strategies for overcoming barriers, suggested tactics to accelerate adoption, and identified several key objectives to support a statewide program:

1. **Increase payer participation.** The majority of California payers are not connected to RxHub, limiting the value of e-prescribing to most providers. The April 2009 Medicare Part D requirement is a critical incentive that can be used to expand payers' ability to provide information about a patient's

insurance eligibility, formulary, and medication history as part of electronic transactions.

2. **Increase pharmacy participation.** Thirty percent of California's retail pharmacies cannot electronically receive or transmit prescriptions. Most connected pharmacies are members of or affiliated with large chains, while smaller and independent pharmacies are less likely to be connected and are thus impeding providers' abilities to route electronic prescriptions to their patients' pharmacies of choice.

3. **Increase provider adoption.** Most of the providers who now use e-prescribing are affiliated with large closed systems. While California's physicians are distributed across urban and rural regions and among various practice sizes and settings, the majority provide patient care in solo and small group practices. Targeted efforts and investments should be made to overcome barriers to adoption in solo and small group practices, including cost and lack of technical support.

4. **Raise awareness and demand among purchasers and consumers.** Communications targeted to the health plans, employers, and consumers outlining the benefits of e-prescribing are limited to a few national initiatives and resources. As more purchasers and consumers understand how e-prescribing can improve convenience, communication, and patient care, they will direct business toward health systems that use electronic methods.

Recommended Approaches for Adoption

Accelerating e-prescribing adoption in California will require a coordinated, multi-stakeholder effort. The approach could focus on three categories: (1) strategies for improving e-prescribing awareness that address privacy issues and education for consumers, providers, and pharmacies; (2) collaboration to ensure alignment of incentives and a shared common vision and objectives; and (3) support for providers and pharmacies to help them implement e-prescribing technology.

Advocacy and Education

To gain traction, e-prescribing initiatives should increase visibility and define the technology's benefits and progress to decisionmakers. In addition, stakeholders could encourage the state to consider modeling a policy on the recent successful federal Medicare legislation, following through on the governor's recommended legislative language outlining specific e-prescribing activities and acting on the recommendations of the Medication Errors Panel.

Stakeholders should create a forum for developing models that describe the benefits of e-prescribing to their constituencies, and guide executive-level understanding and support for e-prescribing programs. A statewide education campaign could help promote understanding of e-prescribing among consumers and purchasers.

Collaboration

Preparing for the broad adoption of e-prescribing will require that providers, payers, and pharmacy organizations find ways to coordinate their efforts and bring their incentives into alignment. Many successful e-prescribing initiatives across the country rely on varying levels of collaboration, ranging from loose affiliations to public-private partnerships with formal governance structures convened under executive mandate.[16] Exploring the spectrum of collaborative models will help determine the appropriate level of public and private stakeholder engagement and investment necessary to develop a statewide e-prescribing program for California.

Program Support

Greater adoption of e-prescribing is predicated upon the development and distribution of technical, implementation, and operational tools for providers and pharmacies. By enabling them to optimize and manage the technology, as well as supporting their willingness to use it, those who have not yet made the switch to e-prescribing may become more open to its possibilities.

Conclusion

California policymakers face a difficult task in spearheading the promotion of e-prescribing and will need to develop a comprehensive strategy to support providers, pharmacies, and patients. While the sheer size and diversity of California's population and health care infrastructure is daunting, coordination of public and private sector initiatives, actions, and programs is necessary.

For their part, California stakeholders must also come together to develop and agree upon a statewide plan that sets forth goals and principles to support e-prescribing and ensure accountability. Such a plan cannot be led by any one stakeholder alone—it is dependent upon all to align their efforts and achieve success.

ABOUT THE AUTHOR

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Kier Wallis, analyst, Manatt Health Solutions

ABOUT THE FOUNDATION

The California HealthCare Foundation is an independent philanthropy committed to improving the way health care is delivered and financed in California. By promoting innovations in care and broader access to information, our goal is to ensure that all Californians can get the care they need, when they need it, at a price they can afford. For more information, visit www.chcf.org.

ENDNOTES

1. Sarasohn-Kahn, J, Holt, M. *The Prescription Infrastructure: Are We Ready for ePrescribing,* California HealthCare Foundation, Oakland, CA. January 2006. Available at www.chcf.org/topics/view.cfm?itemID=118337.

2. National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies. Grant Thorton, LLP. January 2007.

3. Institute of Medicine. *To Err is Human: Building a Safer Health System.* November 1999.

4. Medco Health Solutions Inc., 2008.

5. SureScripts. National Progress Report on E-Prescribing. December 2007. Available at www.surescripts.com/report.

6. SureScripts Pharmacy Health Information Exchange, 2008.

7. Crosson J, Isaacson N, Lancaster D, McDonald E, Schueth A, DiCicco-Bloom B, et al. "Variation in electronic prescribing implementation among twelve ambulatory practices." *Journal of General Internal Medicine.* April 2008. 23(4):364–71.

8. "Options to Increase E-Prescribing in Medicare: Reducing Medication Errors and Generating Up to $29 Billion in Savings for the Federal Government." Gorman Health Group. July 2007.

9. One major step toward achieving greater pharmacy and payer connectivity occurred when SureScripts and RxHub merged on July 1, 2008 to form one single network for the exchange of pharmacy information. SureScripts-RxHub expects to transmit information affecting over 200 million patients in 2008.

10. "RxHub Technology Solution Partners for the Ambulatory Setting." Available at www.rxhub.net/images/pdf/partners/rxhub_technology_solution_providers-ambulatory.pdf.

11. Governor's Health Care Proposal. January 8, 2007. Available at gov.ca.gov/pdf/press/Governors_HC_Proposal.pdf.

12. Medication Errors Panel report. *Prescription for Improving Patient Safety: Addressing Medication Errors.* March 2007. Available at www.cdcan.us/health/medicationserrorpanel-fullfinalreport.pdf.

13. Recognizing that electronic systems alone cannot solve the medication error epidemic in California, the panel also recommended establishing programs to increase consumer education about safe medication practices; creating incentives for pharmacist medication consultation activities; conducting additional training for health care providers; and increasing research on the nature and frequency of medication errors in the state.

14. Department of Health and Human Services. Centers for Medicaid and Medicare Services. Electronic Prescription Drug Program, 42 C.F.R. sec. 423.159 (2008).

15. CA Health and Safety Code § 11164.5.

16. eHealth Initiative and the Center for Improving Medicaid Management. *Electronic Prescribing: Becoming Mainstream Practice.* Washington D.C. June 2008. p. 64.

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             202/778-1036
             pvanderveer@apcoworldwide.com

Health Care Stakeholders Release "How-To" Guide to Help Clinicians Switch from Paper to E-Prescribing Systems

Challenges, Opportunities Await Providers Investing in New Technology

BOSTON, MA - OCTOBER 7, 2008 – The eHealth Initiative (eHI), in collaboration with the American Medical Association, the American Academy of Family Physicians, the American College of Physicians, the Medical Group Management Association, and the Center for Improving Medication Management (Center), issued the first comprehensive, multi-stakeholder-informed "how-to" guide to help clinicians make informed decisions about how and when to transition from paper to electronic prescribing systems. *A Clinician's Guide to Electronic Prescribing* was released at the Centers for Medicare and Medicaid Services (CMS) National e-Prescribing Conference in Boston today and follows the agency's decision earlier this year to offer financial incentives--beginning in 2009--to providers who adopt e-prescribing.

"We know e-prescribing is an efficient way to improve health care delivery, decrease medication errors, and prevent potentially dangerous drug interactions," said eHI Chief Executive Officer Janet Marchibroda. "However, the transition from a paper to electronic system is quite challenging. This guide is meant to remove some of the mystery around e-prescribing and help physicians begin to realize some of the many benefits e-prescribing can bring to their patients and their practices."

Developed with the strategic guidance of a multi-stakeholder Steering Group comprised of clinicians, consumers, employers, health plans, and pharmacies, and in partnership with four major medical associations, the guide is designed to meet the needs of two target audiences: The first section of the guide targets office-based clinicians who are new to the concept of e-prescribing, and who seek a basic understanding of what e-prescribing is, how it works, what its benefits and challenges are, and the current environment impacting its widespread adoption. The second section of the guide targets office-based clinicians who are ready to move forward and bring e-prescribing into their practices. It presents fundamental questions and steps to follow in planning for, selecting and implementing an e-prescribing system. The guide also provides a list of key references and resources readers may consult to help make the transition to e-prescribing as smooth as possible.

"E-prescribing holds great promise for improvements in patient safety and advances in care coordination, and the AMA is committed to helping physicians adopt this technology," said American Medical Association Board Member, Steven J. Stack, M.D. "This guide is an important resource for physicians and can aid in the adoption and implementation of e-prescribing."

"With all the momentum toward e-prescribing and its accelerated growth, it is important to assist physicians and other prescribers to ensure that e-prescribing is implemented well in order for the full range of benefits can be achieved," said Steven E. Waldren, MD, MS, Director, Center for Health-IT at the American Academy of Family Physicians and Center for Improving Medication Management Board member. "This Guide provides substantial detail not only on how to get started but what challenges to expect and how to overcome them."

In June, eHI and the Center for Improving Medication Management released a report detailing the latest figures on e-prescribing, including the progress made, the obstacles that remain, and recommendations for how different stakeholders in the system can support the migration from paper-based prescriptions to an electronic system. Among the findings from the report were the following:

- More than 35 million prescription transactions were sent electronically in 2007, a 170 percent increase over the previous year.

- At the end of 2007, at least 35,000 prescribers were actively e-prescribing. Estimates indicate there will be at least 85,000 active users of e-prescribing by the end of 2008.

- While e-prescribing is growing rapidly, the adoption level at the end of 2007 represents only about six percent of physicians.

- Only two percent of eligible prescriptions were transmitted electronically in 2007.

- The biggest challenges to widespread adoption of e-prescribing by providers are financial burdens, workflow changes, continued needs for improved connectivity and technology, and the need for reconciled medication histories.

Accompanying the June report were corresponding guides that offer practical information for health care payers to support effective adoption, and for consumers to better understand e-prescribing's benefits and use.

The full prescriber guide and the earlier e-prescribing reports are available at www.ehealthinitiative.org.

# # #

About eHealth Initiative and its Foundation
The eHealth Initiative and its Foundation are independent, non-profit affiliated organizations whose missions are to drive improvements in the quality, safety, and efficiency of healthcare through information and information technology. eHI engages multiple stakeholders, including clinicians, consumers, employers, health plans, health IT suppliers, hospitals and other providers, laboratories, pharmaceutical manufacturers, pharmacies, and state and local leaders to reach agreement on and drive the adoption of common principles, policies and best practices for improving health and health care through information technology. For more information, visit www.ehealthinitiative.org.

About the Center for Improving Medication Management
The Center for Improving Medication Management serves as an industry resource by gathering and disseminating best and worst practices related to technology deployment for electronic medication management and for leveraging that technology and connectivity to test innovative approaches to improve patient adherence with prescribed medications. The Center was founded by the American Academy of Family Physicians, Blue Cross Blue Shield Association, Humana Inc., Intel Corporation, the Medical Group Management Association, and SureScripts-RxHub. For more information, visit www.thecimm.org.

About American Medical Association
The American Medical Association (AMA) helps doctors help patients by uniting physicians nationwide to work on the most important professional, public health and advocacy issues in medicine. Working together, the AMA's quarter of a million physician and medical student members are playing an active role in shaping the future of medicine. For more information, visit www.ama-assn.org.

**About the American Academy of Family Physicians**
The American Academy of Family Physicians is one of the largest national medical organizations, representing more than 94,000 family physicians, family medicine residents, and medical students nationwide. Founded in 1947, AAFP's mission has been to preserve and promote the science and art of family medicine and to ensure high-quality, cost-effective health care for patients of all ages. For more information, visit www.aafp.org.

About the American College of Physicians
The American College of Physicians (ACP) is a national organization of internists - physicians who specialize in the prevention, detection and treatment of illnesses in adults. ACP is the largest medical-specialty organization and second-largest physician group in the United States. Its membership of 126,000 includes internists, internal medicine subspecialists, and medical students, residents, and fellows. ACP's mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine. For more information, visit www.acponline.org.

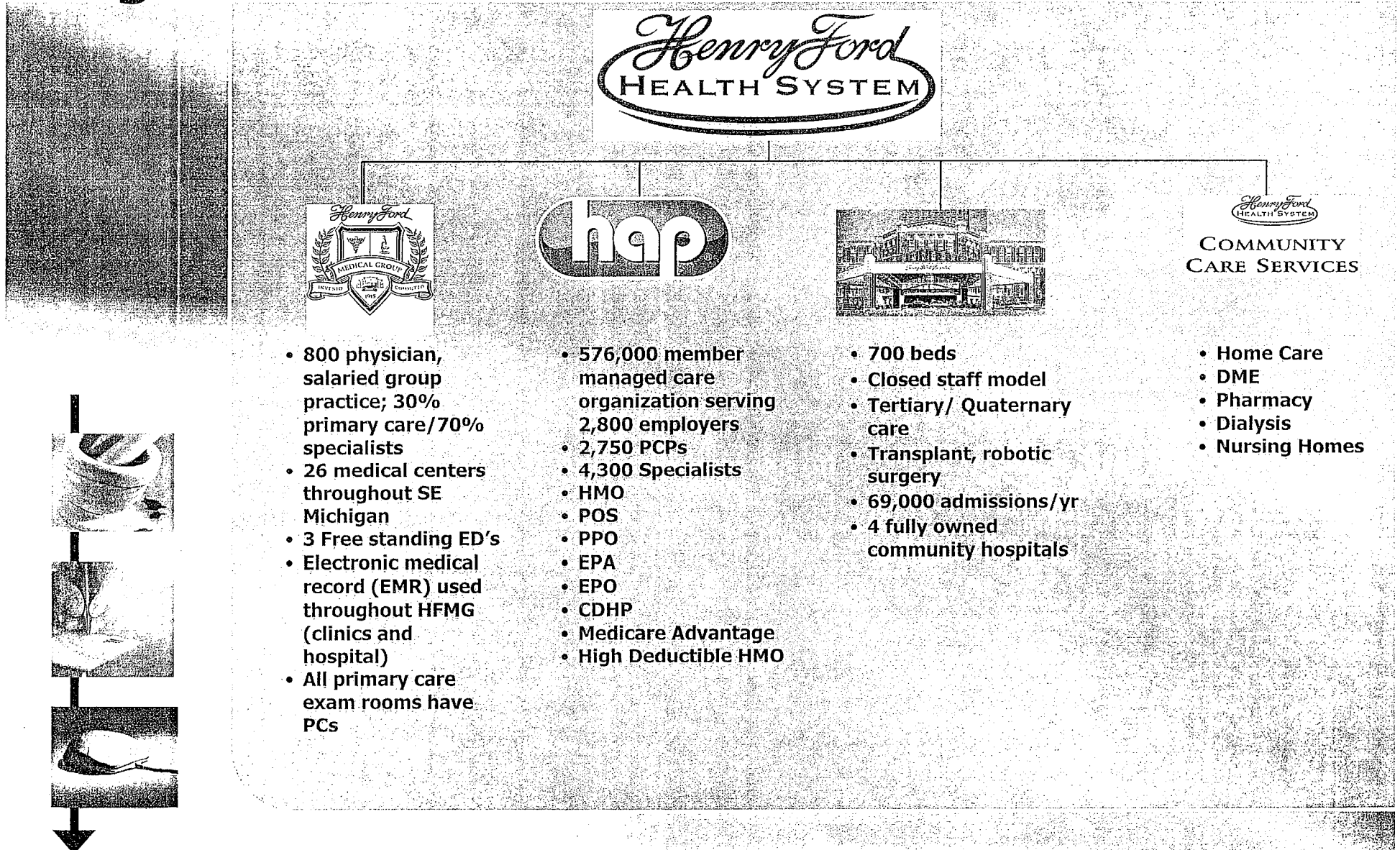**About the Medical Group Management Association (MGMA)**
The Medical Group Management Association (MGMA) is the nation's principal voice for the medical group practice profession, with 21,500 members who lead and manage more than 13,500 organizations in which almost 270,000 practice. MGMA's mission is to continually improve the performance of medical group practice professionals and the organizations they represent. For more information, visit www.mgma.com.
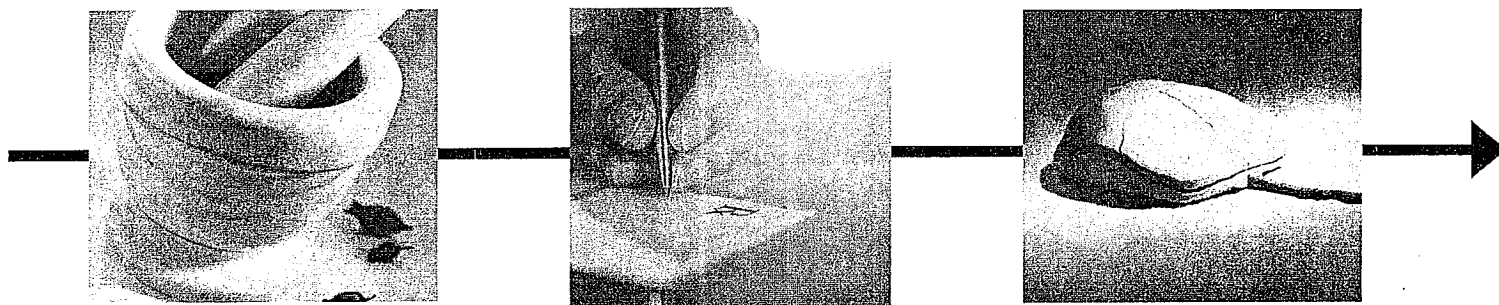
ePrescribing Success in Michigan – Henry Ford Health System

Henry Ford
HEALTH SYSTEM

hap

Henry Ford Health System Overview – Organizational

- 800 physician, salaried group practice; 30% primary care/70% specialists
- 26 medical centers throughout SE Michigan
- 3 Free standing ED's
- Electronic medical record (EMR) used throughout HFMG (clinics and hospital)
- All primary care exam rooms have PCs

- 576,000 member managed care organization serving 2,800 employers
- 2,750 PCPs
- 4,300 Specialists
- HMO
- POS
- PPO
- EPA
- EPO
- CDHP
- Medicare Advantage
- High Deductible HMO

- 700 beds
- Closed staff model
- Tertiary/ Quaternary care
- Transplant, robotic surgery
- 69,000 admissions/yr
- 4 fully owned community hospitals

COMMUNITY CARE SERVICES

- Home Care
- DME
- Pharmacy
- Dialysis
- Nursing Homes

Henry Ford Health System Overview – Statistics

- 3.2 million patient visits/year and more than 78,000 outpatient surgical procedures/year
- More than 1 million SE Michigan residents receive from HFHS
- 20% of ambulatory care and 10% of acute care services in southeast Michigan is provided by HFHS
- $3.8 billion in revenue in 2006; net income $154 million; $104 million in uncompensated care
- Primary payor distribution:
  - 27% Medicare
  - 22% Health Alliance Plan (HAP)
  - 17% BCBS MI
  - 10% Medicaid

HFHS ePrescribing Initiative – History

- **September 2004** – GM asked HAP & HFMG to partner with auto companies to test ePrescribing via the Southeast Michigan ePrescribing Initiative (SEMI). HFMG agreed to be the incubator for testing ePrescribing and eight HFMG primary care clinics launch ePrescribing

- **January 2005** – HFMG/HAP launched first 4 HFMG primary care clinics on ePrescribing

- **April 2005** – Due to demonstrated benefit, HFMG decides to spread ePrescribing to entire medical group

- **January 2006** – HFMG completed implementation at all primary care clinics

- **January 2007** – HFMG completed implementation in all outpatient specialty care clinics

- **February 2007** – Michigan is recognized for moving from the 10th highest ePrescribing state to the 6th for 2006

- **April 2007** – HFMG launches 3 Emergency departments on ePrescribing

- **February 2008** – Michigan is recognized for moving from the 6th highest ePrescribing state to the 5th for 2007
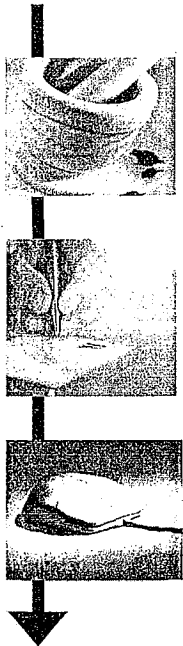
ePrescribing: Value Proposition for HFHS

The Institute of Medicine's (IOM) 2001 Crossing the Quality Chasm report identified six critical dimensions of quality in healthcare. ePrescribing for HFHS impacts at least 4 of them

- Safe
- Efficient
- Effective*
- Patient centered*
- Timely

Definition

- Safe - avoiding injuries to patients from care that is intended to aid
- Efficient - avoiding waste of equipment/supplies, and resources
- ...avoiding underuse and overuse
- Patient centered - providing care that is responsive to patient values and needs

ePrescribing Results at HFMG – Safe
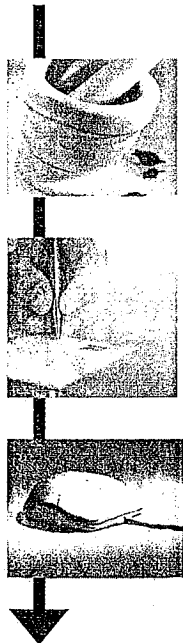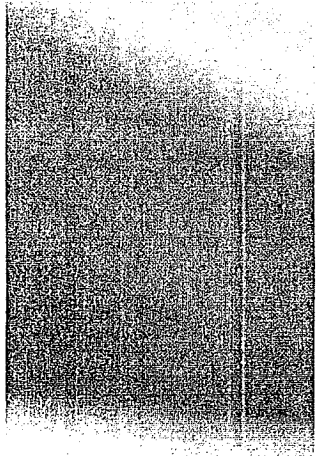
- Over <u>420,000</u> prescriptions changed or cancelled due to drug to drug interaction warnings

- Over <u>31,000</u> prescriptions changed or cancelled due to drug/allergy warnings

- HAP prescription claims for HFMG patients were analyzed for incidences of claims for drug combinations considered severely contraindicated[1]

- Comparing the pre/post, there was a **24% reduction** in the incidence of patients with prescription claims for severely contraindicated medications (warfarin and erythromycin, insulin and propranolol, lithium and thiazides, etc.)

- There was also a **48% reduction** in the incidence of pregnant women who had prescription claims for severely contraindicated medications during pregnancy (coumadin, heparin, oral diabetic agents, etc.)

[1] Solberg, Leif I., MD, et. al, "Measuring Patient Safety in Ambulatory Care: Potential for Identifying Medical Group Drug-Drug Interaction Rates Using Claims Data", American Journal of Managed Care, Nov 2004.

ePrescribing Initiative – Efficient

Sources of inefficiency, error and rework in paper-based refill process

Patient calls for medication refill

↓

Customer Service Rep (CSR) writes information for nurse/doctor review and action

↓

Doctor or doctor's agent (nurse) reviews prescription and makes decision for fill or not

↓

Doctor or agent calls pharmacy with prescription information, information documented in the medical record

↓

Pharmacy fills prescription and patient picks it up

1. Patient gives wrong information or doesn't have information (I,E,R)
2. CSR incorrectly copies information (E,R)
3. Written information is misplaced and not seen by doctor (R)
4. Chart misplaced or slow to be located/retrieved (I,R)
5. Review time in chart (I)
6. Correct phone number for pharmacy needed (E,R)
7. Time spent on phone with pharmacy (I)
8. Transcription error at pharmacy (E,R)
9. Transcription error in medical record or not recorded (E,R)
10. Patient fails to get prescription (I,R)
11. Patient fails to notice error (E)

I=Inefficiency, E=Error, R=Rework
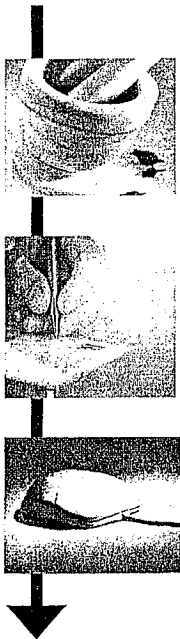
ePrescribing Value Drivers – Efficient

Sources of improved efficiency and decreased error

| Pharmacy sends refill request electronically | Patient calls for medication refill |

↓

Electronic request sent to a clinic "in box" for review by doctor or doctor's agent and decision on action

↓

Prescription automatically sent to pharmacy and documented

↓

Pharmacy fills prescription and patient picks it up
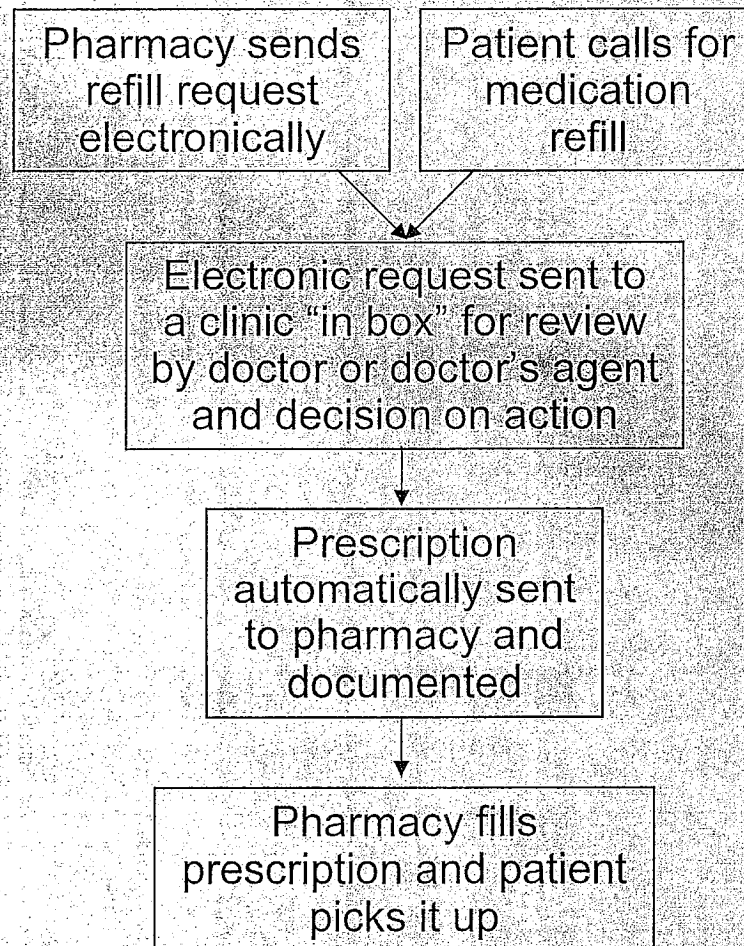
1. Greatly reduced time and no transcription errors
2. Information on patient available as prescription created
3. Requests not lost
4. Information available as decision made
5. Enormous time savings
6. No transcription error
7. Reliable documentation
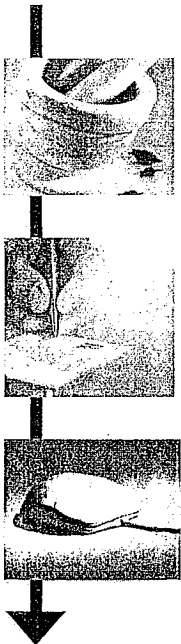
ePrescribing Value Drivers – Efficient

	New Prescription	Renewal
Exam Room	Provider: ☹	Provider: ☺ MA/Nurse: ☺
Phone Call / Fax	Provider: ☺ MA/Nurse: ☺ CSR: ☺	Provider: ☺ MA/Nurse: ☺ ☺ CSR: ☺

- ❑ <u>4,500,000</u> PRESCRIPTIONS SENT ELECTRONICALLY TO DATE
- ❑ Over 35,000 prescriptions generated per week

ePrescribing Value Drivers – Effective and Patient-Centered

- Effective
    - Over <u>115,000</u> prescriptions changed or cancelled due to formulary warnings
    - HFMG has improved its HAP generic use rate overall from <u>56.7% to 74.8% (32% improvement)</u>

- Patient-Centered
    - 70% agree that ePrescribing improves patient satisfaction
    - Patients report satisfaction with expedited handling of renewals at doctor's office, elimination of script drop off, and reduction in wait times at pharmacy
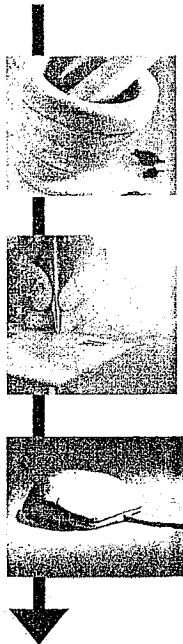
Achievements – Return on Investment

- HAP/HFMG initial capital investment of $1.6 million plus annual operating costs averaging $590,000 reaps total savings of more than $1.9 million in total for 2005 and 2006

- Future estimated savings through 2009 will average $4 million per year

- Based on the 2005 and 2006 realized improvement in generic use rate, the five year Return On Investment is now estimated to be over $14M

- Key sources of cost reduction benefit are:

  - **GUR Improvement** – totaling $1.5 million for 2005 & 2006 and estimated at $3 million/year for 2007-2009

  - **Administrative savings** – totaling $700,000 for 2005 & 2006 and estimated at $560,000/year for 2007-2009

  - **Estimated impact of reduced adverse drug events (ADEs)** – totaling $540,000 for 2005 and 2006 and $540,000/year for 2007-2009
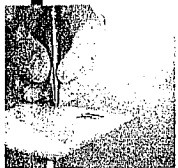
Keys to Implementation Success


```
Demo → Tech Assessment → Process Assessment → Data Conversion / Registration → IT Install → Training → Support
```
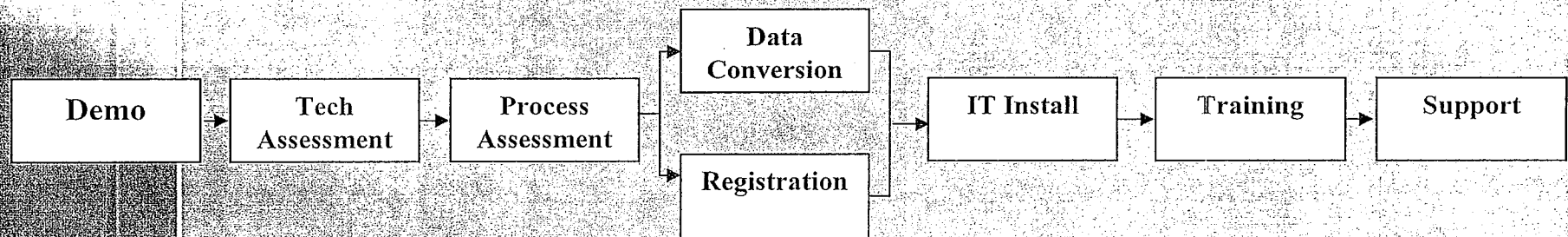
- Setting the Stage
- Feet on the Street
- Vendor Selection
- Pilot Site Selection
- Clinic Assessment
- Process/Roles/Workflow mapping
- Equipment
- Data / IT integration
- Training and Support

ePrescribing Expansion –
Taking Lessons Learned to Independent Physicians

- United Physicians / PPN
  - 1,864 physician IPA with 476 PCPs; focused primarily in Oakland and Macomb counties
  - 46,000 HAP members

- Huron Valley Physicians Association
  - 600 physician IPA with 150 PCPs; focused primarily in Washtenaw county
  - 11,000 HAP members

ePrescribing Expansion – Independent Physicians

The chart below shows the overall utilization of ePrescribing by the networks HAP has partnered with directly

January 2005 – September 2008

Network	# of Physicians	Total Scripts	D/D Cancels[1]	%	D/A Cancels[2]	%	Formulary Cancels/ Changes[3]	%
HFMG	900	4,728,000	484,000	10.2	35,000	.7	122,000	2.6
UP	490	699,000	38,000	5.4	3,800	.5	12,600	1.8
HVPA	81	136,000	23,000	16.9	4,000	2.9	2,800	2.1
CIPA (w/ SE MI)	31	*	*	*	*	*	*	*
Total	1,501	5,563,000	545,000	9.8	42,800	.8	137,400	2.5

1 - Cancels = prescriptions cancelled by prescriber base on drug to drug warning received while prescribing

2 - D/A Cancels = prescriptions cancelled by prescriber base on drug allergy warning received while prescribing

3- Formulary Cancels/Changes - prescriptions cancelled/changed by prescriber based on formulary warning received while prescribing

* - not tracked at the SE MI region level
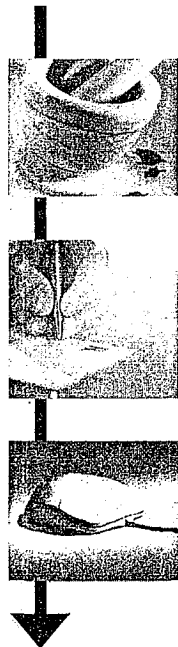
SEMI ePrescribing Initiative
High Level Project Plan

Phase One (2005-06) → **Phase Two (2006-07)** → **Phase Three (2007-08)**

Infrastructure
- Built All-Payer Network
- Chose Portfolio of Vendors
- Educated the Community
- Identified Physician Leaders or Champions
- Incentives – philosophy "Skin in the Game"
  - $500/MD participant

Adoption
- IPA/PO/Group Recruitment
- Leveraged Network
- Community Outreach
- Implement/Training
- Performance-based Incentives
  - $1,000/MD participant
    - $500 after install
    - $500 after 6 mos of continuous use

Utilization
- Convert non- or low-utilizers to cont users
- Support phase 2 commitments
- Recruit new physicians
- Continue Performance-based Incentives
  - $1,000/MD participant
    - $500 after install
    - $500 after 6 mos of continuous use

ePrescribing User Assessment Study

Objective: Current Understanding of User Experiences

- There were 500 completed surveys
- For 9 of 10 users, their eRx system either met or exceeded expectations

- Other key findings:
  - Nearly 70% highly agree that ePrescribing improves quality of care
  - Almost 75% highly agree that ePrescribing improves patient safety
  - Approximately 70% were very satisfied with the ease of identifying drug-related interactions
  - More than 60% of physicians report at least one incident of changing a prescription in response to a safety alert
  - 71 percent highly agree that a patient's transaction at the pharmacy is faster and easier
  - More than 70% have seen a reduction in phone calls / faxes to / from pharmacies since using the eprescribing system
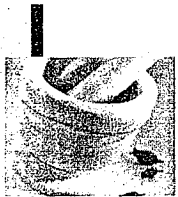
Other Findings
ePrescribing Physician Assessment Study

- Most Frequently Cited Benefits
  - Helps me document or obtain prescription history (8.4/10)
  - Improves patient safety (8.3/10)

- Processes with Highest Satisfaction
  - Ease of managing renewal requests (8.5/10)
  - Drug-to-allergy (8.3/10) and drug-to-drug (8.2/10) interactions

- Most Desired Enhancements
  - Ability to indicate if a drug requires prior authorization (9.0/10)
  - Ability to manage prior authorization electronically (9.0/10)

- Most Suggested Improvements
  - Make prior authorization available online
  - More accurate pharmacy information

MIPAA - New Medicare Incentives

- Administered through Physician Quality Reporting Initiative (PQRI) in 2009

- Requires that physician uses a qualified ePrescribing system:
  - Generate medication list
  - Select medications, transmit prescriptions and conduct safety checks*
  - Provide information on lower cost alternatives
  - Provide information on formulary or tiered formulary medications, patient eligibility and authorization requirements received electronically from the patient's drug plan

*Safety checks: provider authorization, active medications, check dose and strength for the drug being prescribed, potential adverse reaction at point of administration of the drug, drug-drug interactions, allergy concerns, and warnings/cautions
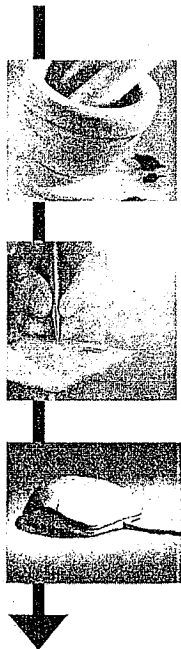
New Medicare Incentives

Quality "Stick" Incentive Model
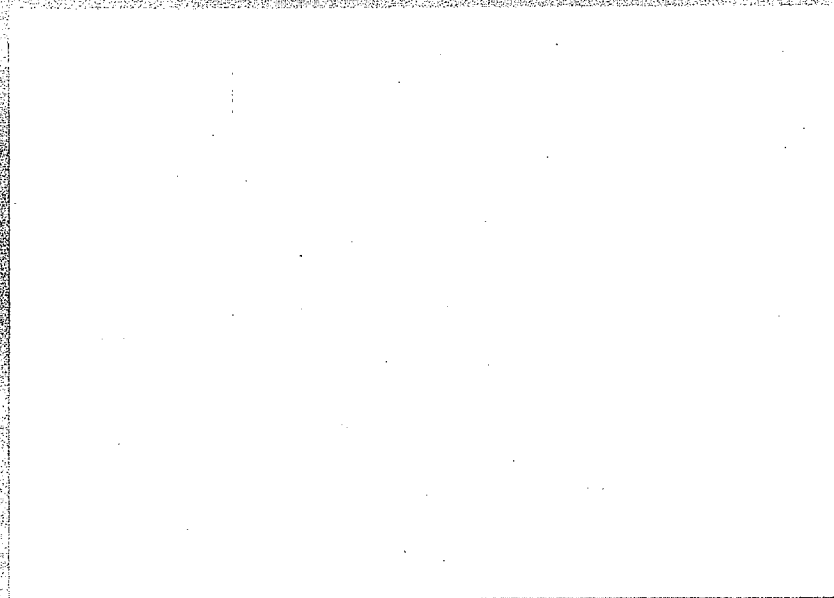
Successful reporting is defined as reporting the measure on at least 50% of the eligible patients

Individual CPT codes that make up the denominator account for at least 10% of professional/allowed charges for Medicare B and B covered services
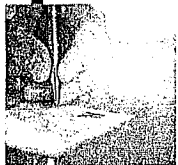
Questions??
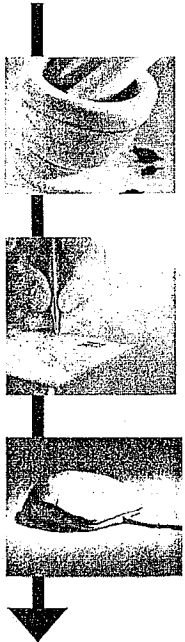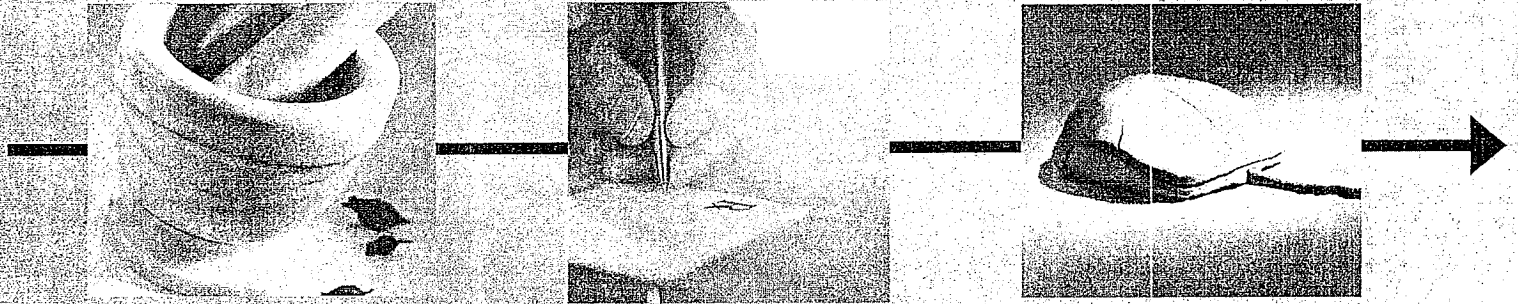
A CLINICIAN'S GUIDE TO ELECTRONIC PRESCRIBING

eHEALTH INITIATIVE
Real Solutions, Better Health

THE CENTER
for
Improving Medication Management
A collaborative of providers, payors, employers and pharmacies

AMA
AMERICAN
MEDICAL
ASSOCIATION

AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

ACP
AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | Doctors for Adults

MGMA
Medical Group
Management Association

OCTOBER • 2008

Foreword

Dear Colleagues:

The eHealth Initiative Foundation, in collaboration with the American Medical Association, the American Academy of Family Physicians, the American College of Physicians, the Medical Group Management Association, and the Center for Improving Medication Management are pleased to present "A Clinician's Guide to Electronic Prescribing," the third in a series of practical guides. These guides are designed to educate key stakeholders about e-prescribing and the steps involved in its adoption. These guides, written for consumers and health care payers, complement our June 2008 report "Electronic Prescribing: Becoming Mainstream Practice". The report provides an update on progress made in e-prescribing over the last four years and a description of barriers that must be overcome to make e-prescribing the standard of care throughout the U.S. health care system.

"A Clinician's Guide to Electronic Prescribing" is designed for two target audiences:

(1) Practices new to e-prescribing and who want an overview of what it is.

> Section I of the guide provides basic information on what electronic prescribing is, how it works, its benefits and challenges, and the current status of adoption.

(2) Practices that are ready to move forward with implementing e-prescribing, and already have a good grasp of the fundamentals provided in Section I of the guide.

> Section II is geared toward office-based clinicians who are ready to bring e-prescribing into their practices. This section provides guidance on the steps to take and pitfalls to avoid. It presents essential questions and considerations for planning, selecting, and implementing an e-prescribing system.

The guide also provides a list of key references and resources readers can consult to help make the transition to e-prescribing as smooth as possible.

To ensure the guide fully addressed the perspective and needs of prescribers, four medical associations played a central role in its development: the American Medical Association, the American Academy of Family Physicians, the American College of Physicians, and the Medical Group Management Association. In addition, a multi-stakeholder Steering Committee comprised of clinicians, consumers, employers, health plans, health information technology companies, and pharmacies, ensured the guide offers a balanced picture of e-prescribing, and the role that different organizations play in assuring its effective adoption.

We believe this guide will be an invaluable resource for clinicians. It is our hope that this guide will help encourage growth in the use of e-prescribing technology—technology that can make it safer for patients to take their prescribed medicines, lowers the overall cost of care, and streamlines the handling of prescriptions for both prescribers and pharmacies.

Table of Contents

SECTION I: OVERVIEW OF E-PRESCRIBING

What Is E-Prescribing?

Electronic prescribing, or "e-prescribing" is the computer-based electronic generation, transmission and filling of a prescription, taking the place of paper and faxed prescriptions. E-prescribing allows a physician, nurse practitioner, or physician assistant to electronically transmit a new prescription or renewal authorization to a community or mail-order pharmacy.

A more formal definition of e-prescribing is provided in the Medicare Part D prescription drug program:

> *E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.*

In 2009 Medicare will begin a program for clinicians, offering a financial incentive for those prescribers using a "qualified" e-prescribing system. A "qualified" e-prescribing system must be capable of performing all of the following functions:

- Generating a complete active medication list incorporating electronic data received from applicable pharmacy drug plan(s) if available
- Selecting medications, printing prescriptions, electronically transmitting prescriptions, and conducting all safety checks (safety checks include: automated prompts that offer information on the drug being prescribed, potential inappropriate dose or route of administration, drug-drug interactions, allergy concerns, or warnings or cautions)
- Providing information related to the availability of lower cost, therapeutically appropriate alternatives (if any)
- Providing information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan

Most e-prescribing systems and many electronic health record systems (EHR systems) on the market today offer the above capabilities. Specific standards required to e-prescribe under Medicare Part D are further discussed below, and are also referenced in Appendix I. As used in this guide, e-prescribing encompasses clinical decision support to aid in safer, more informed prescribing such as access to information on drug-drug interactions, drug-allergy interactions, patient medication history, pharmacy eligibility, formulary (which specifies a patient's drug coverage), and benefits information. Electronic prescribing should be seen as an important step in improving patient care, with an eye toward moving to implementation of a complete EHR system.

More information and resources to help you select an e-prescribing system that fits your practice's needs are provided in Section II of this guide.

What Are My Choices for An E-Prescribing System?

There are two choices available when you consider e-prescribing system: either a stand-alone system, or e-prescribing within an EHR system. There are pros and cons of each option in terms of cost, level of effort and time to select and deploy, impact on practice workflow and productivity initially and over time, and interoperability with other electronic health information systems. Section II of this guide provides detailed guidance on the advantages and disadvantages of each option, both from a short term and longer range perspective, to help you select the option that best fits your practice's needs.

1) A stand-alone system is less costly and less complex to implement, and thus can be implemented more quickly than an EHR system. This may be an important consideration for practices that wish to be eligible for Medicare's e-prescribing bonus that begins on January 1, 2009. E-prescribing systems store and manage patient data specific to the prescribing process (e.g., medication history, medication allergies, etc.). E-prescribing software is offered in two forms: (a) a software package you acquire and download to your office computer system, or more commonly; (b) through the Internet, connecting with an e-prescribing software application service provider (ASP), to whom you pay usage fees.

In terms of e-prescribing hardware, physician practices have many choices including: hand-held devices, tablet personal computers, desktop personal computers, and other hardware made available by technology vendors.

Many believe that a stand-alone e-prescribing system can serve as a pathway to an EHR system, allowing prescribers to become more technologically proficient and comfortable with using electronic systems to support and improve patient care. When implementing a stand-alone system, it is important to plan how you will eventually transition to an EHR system.

2) An EHR system with an integrated e-prescribing module offers the advantage of having immediate electronic access to all patient data stored in the EHR system, including diagnoses, problem lists, clinical notes, laboratory and radiology results and orders, adding to a clinician's ability to make the most informed medication choices for their patients. EHR systems may also often offer a broader range of clinical decision support, including notification of needed screening tests, immunizations, etc.

Physician practices are increasingly using e-prescribing within an EHR system, due to the EHR system's more comprehensive functionality, which enables greater gains in quality and safety. Currently, more than 50 EHR systems offer integrated e-prescribing. For practices that are committed to full automation and interoperability with other providers and sources of patient information, an EHR system with e-prescribing would be the better choice.

EHR systems are significantly more costly and complex to implement than stand-alone e-prescribing applications.

Important Note: To comply with Medicare's e-prescribing regulations and be eligible for the e-prescribing bonus, be sure the e-prescribing system you select meets ALL Medicare Part D e-prescribing standards which will be in effect as of April 1, 2009. These standards can be found at: http://www.cms.hhs.gov/EPrescribing.

Why Should I E-Prescribe? What Are the Benefits?

E-prescribing offers clinicians a powerful tool for safely and efficiently managing their patients' medications. Compared to paper-based prescribing, e-prescribing can enhance patient safety and medication compliance, improve prescribing accuracy and efficiency, and reduce health care costs through averted adverse drug events and substitution of less expensive drug alternatives. Taken together, these impacts translate to a higher quality, more efficient health care system that benefits all.

More specifically, e-prescribing can benefit your patients and practice by:

1) Improving patient safety and quality of care. There are a number of ways e-prescribing can reduce medication errors and resultant adverse drug events:

- **Illegibility** from hand-written prescriptions is eliminated, decreasing the risk of medication errors and decreasing liability risks.
- **Oral miscommunications** regarding prescriptions can be reduced, as e-prescribing should decrease the need for phone calls between prescribers and dispensers.
- **Warning and alert systems** are provided at the point of prescribing. E-prescribing systems can enhance an overall medication management process through clinical decision support systems that can perform checks against the patient's current medications for drug-drug interactions, drug-allergy interactions, diagnoses, body weight, age, drug appropriateness, and correct dosing; and alert prescribers to contraindications, adverse reactions, and duplicate therapy. E-prescribing software may also include drug reference software programs, such as ePocrates Rx, Pro, and the Physicians' Desk Reference.
- **Access to patient's medical and medication history.** Having the patient's medical and medication history from all providers at the time of prescribing can support alerts related to drug inappropriateness in combination with other medications or with specific medical problems.

2) Reducing time spent on phone calls and call-backs to pharmacies. Physician offices receive over 150 million call-backs from pharmacies with questions, clarifications and renewal requests. Medco® Health Solutions, Inc. conducted a survey of Boston area physicians and 88% of those surveyed said they, or their staff, spend almost one-third of their time responding to phone calls from pharmacies regarding prescriptions. E-prescribing can significantly reduce the volume of pharmacy call-backs related to handwriting legibility, mistaken manual prescription choices, formulary and pharmacy benefits, positively impacting office workflow efficiency and overall productivity.

3) Reducing time spent faxing prescriptions to pharmacies. Both prescribers and pharmacies can save time and resources spent on faxing prescriptions, reducing labor, handling, unreliability, and paper expense with e-prescriptions.

4) Automating the prescription renewal request and authorization process. Using e-prescribing, renewal authorization can be an automated process that provides efficiencies for both prescribers and pharmacies. The staff in the pharmacy generates a renewal request/authorization that is delivered through the network to the prescriber's system; the prescriber then reviews and approves/denies the request, and responds electronically to update the pharmacy system. With only a few clicks, prescribers can complete renewal authorization tasks, document that activity and create related staff orders.

5) Increasing patient convenience and medication compliance.
It is estimated that 20% of paper-based prescription orders go
unfilled by the patient—at least in part due to the hassle of
dropping off a paper prescription and waiting for it to be filled.
By eliminating or reducing this wait, e-prescribing may help
reduce the number of unfilled prescriptions. Allowing electronic
renewal requests can also improve the efficiency of this process,
reducing obstacles that may result in less patient compliance.
Availability of information on when patients' prescriptions are filled
can help clinicians evaluate and address issues of patient
compliance as well.

**6) Improving formulary adherence permits lower cost drug
substitutions.** By checking with health plan/insurer formularies
at the point of care, generic substitutions or lower cost therapeutic
equivalent medications can be encouraged and help reduce patient
costs. Lower cost for patients can also help improve medication
compliance.

> Recent research by the
> American Medical
> Association found that, due
> to these benefits,
> physicians who use an
> e-prescribing system are
> significantly more satisfied
> with their prescribing
> process than physicians
> who continue to handwrite
> prescriptions. For a
> summary of this research,
> go to www.ama-assn.org/
> go/hit.

7) Allowing greater prescriber mobility. Improved prescriber convenience can be
attained when using a mobile device (laptop, PDA, etc.) and wireless network to write or
authorize prescriptions. This allows prescribers to write prescriptions anywhere, even when
not in the office.

8) Improving drug surveillance/recall ability. E-prescribing systems enable automated
analytical queries and reports, which would be impossible with a paper prescription system.
Common examples of such reporting would be: finding all patients with a particular
prescription during a drug recall, or the frequency and types of medication prescribed by
certain providers.

What Are the Challenges to E-Prescribing Adoption?

E-prescribing can streamline work processes and make the system run efficiently if the
right tools are available in the right setting. Change can be difficult; however, e-prescribing
may enable your practice to more effectively manage medications for your patients.

Challenges that have hindered more widespread adoption are described below. For those
who decide to go forward with e-prescribing, Section II of this guide addresses these
challenges and obstacles in greater detail, and offers guidance and strategies for making
your transition to e-prescribing as smooth and trouble free as possible.

1) Financial Cost and Return on Investment (ROI): Prescribers, especially those in
small practices and in inner city or rural settings, may believe they bear more than their fair
share of the cost of e-prescribing, since other stakeholders also benefit from the savings
and quality improvements that are achieved, or receive fees from the use of e-prescribing.
Physician practices need to invest in hardware and software, and cost estimates vary
depending on whether an EHR system is adopted or a stand-alone e-prescribing system is
used. Even physicians receiving free e-prescribing systems may face financial costs in the
areas of practice management interfaces, customization, training, maintenance, and
upgrades as well as time and efficiency loss during the transition period. Large urban
practices have been the sites of most successful implementations and can achieve a
positive ROI in as little as 1-2 years for e-prescribing and EHR systems, but it may take
longer for small practices in rural and inner city settings to achieve a ROI.

2) Change Management: It is important not to underestimate the change management challenges associated with transitioning from paper prescribing to e-prescribing. In a busy practice setting where providers and their staff are accustomed to their current management of patient prescriptions, change management is important. Furthermore, if some of the providers and staff are particularly technology averse, it can be difficult to get everyone onboard with such a dramatic change. It is difficult and time consuming for practices to figure out how to change workflow around the management of prescriptions when e-prescribing or EHR systems are introduced. The change requires adequate planning, training, support, and continuous quality improvement for effective management.

3) Workflow: New systems, particularly in the beginning, are likely to add time to tasks like creating new prescriptions or capturing preferred pharmacy information at patient intake, and this can be a barrier. Workflow changes are greater with a full EHR system as compared to stand-alone e-prescribing systems, but either way, practices often experience lost productivity during the transition while they modify the practice workflow and become adept at using the system. In addition, roles and responsibilities in the practice may change, such that activities that staff handled in the past (such as preparing a paper prescription for signature) may need to be taken on by physicians. Despite the fact that efficiencies and time savings can be gained within the practice by automating renewal authorizations, workflow change remains difficult. Practices (especially small practices) would benefit from additional resources to support them during this transition and to help them know where to turn when they encounter issues.

4) Controlled Substances: Because the DEA currently prohibits electronic transmission of prescriptions for controlled substances, both physician practices and pharmacies are forced to use different workflows to manage these prescriptions. This adds complexity to the prescribing process and is a barrier to adoption and use of e-prescribing, given that, according to AMA estimates, about 20% of all prescriptions are for controlled substances. Typically, the vendor system forces prescriptions for controlled substances to be printed. A specific type of registered paper may be required and some systems can be set up to print the prescription on printer friendly versions of this registered paper that the clinician then must manually sign. This requires either a separate dedicated printer or a specialized printer that can switch to the specialized paper on demand. The printer must also be kept in a secure area. The provider can still use his e-prescribing or EHR system to generate and document all prescriptions; however, prescriptions for controlled substances cannot be transmitted electronically. In the summer of 2008, the DEA issued a proposed rule to allow controlledsubstances to be e-prescribed, and public comments on the proposed rule were due September 25, 2008.

5) State Regulatory Restrictions: Although all states allow electronic prescribing, there remain some regulatory restrictions to be resolved. An example is the requirement by Medicaid in New York State to have "dispense as written (DAW)" in a handwritten form. There are many ongoing efforts in place to resolve these issues.

6) Hardware and Software Selection: Choosing the right software and hardware and supporting it after installation can be a daunting task for some physician practices, especially small practices that are extremely busy, experiencing declining reimbursements, and lack expert information technology staff. Some struggle with how to get started, vendor selection, negotiation, implementation and long term support. Section II of this guide will help you decide what kind of system will best fit your practice, and how to go about selecting and deploying the system you choose.

7) Limitations on E-Prescribing System Remote Access: There is often no easy remote access options. In rural areas there may not be many options for consistent remote access services due to cell phone gaps for digital service and limitations of broadband Internet service.

8) Pharmacy, Payer/PBM and Mail Order Connectivity: Not all pharmacies are connected to SureScripts-RxHub—about 3% of chain pharmacies have yet to be connected and approximately 73% of independent pharmacies are not connected even though the vast majority of them are using certified software. Some pharmacies who already have e-prescribing capabilities may be unwilling to "switch on" e-prescribing capability until there is a sufficient number of e-prescribers in their area, because they do not want to pay a fee for each prescription received electronically. Not all payers/PBMs are connected to deliver formulary, eligibility, or medication history information, and not all mail-order pharmacies are electronically connected. Few Medicaid systems participate. While the majority of payers and PBMs are connected (representing about 200 million lives), if the formulary, eligibility, or medication history information is not comprehensive enough, prescribers may choose not to look at the data because they do not have confidence in its accuracy or completeness. Lastly, e-prescribing in rural areas can be more difficult if there is a lack of broadband Internet access.

9) Medication History and Medication Reconciliation: E-prescribing can help provide information to prescribers at the point of care on what medications their patients are taking, and have taken in the past. However, it is difficult to place absolute confidence in the completeness and currency of this information, since medication histories must be reconciled from multiple sources. Prescribers should always consult with their patients about what medications they are taking to validate the medication history information that is available through e-prescribing and update the records accordingly.

10) Medical History Information: Not all stand-alone e-prescribing systems include other patient medical history information (such as a problems list), which could impact a prescriber's medication decisions. This type of information would be included in an EHR system with e-prescribing.

11) Prescribing from Multiple Office Sites: It is important for an e-prescribing system to be able to accommodate the handling of prescriptions when the prescriber uses multiple office sites, since there are often different prescriber registration numbers, passwords, etc. that are site specific. In addition, it is important to be able to view and manage patient records from one site while working elsewhere. This functionality is not always available in all systems.

12) Small/Rural Practice Challenges: The above challenges generally apply to most practice types, but some challenges are magnified for small or rural practices. Rural practices face a particular set of challenges in e-prescribing, including lack of access to broadband connectivity and to skilled information technology professionals who can help them with hardware selection and maintenance. As a result of these many challenges, the ROI for these practices takes much longer.

13) Patient Acceptance/Usage Issues: Some patients may not feel comfortable with electronic prescriptions and demand their clinician provide a paper prescription. Also, patients who travel frequently, or are otherwise away from home for extended periods may feel more comfortable having a written prescription to take with them.

The Electronic Prescribing Landscape Today

Of the 1.47 billion new and renewal prescriptions eligible for electronic routing, only about 2% or 35 million were transmitted electronically in 2007, with 35,000 clinicians using this technology. These figures are projected to nearly triple in 2008, with e-prescriptions rising to 100 million, and the number of e-prescribers increasing to 85,000, or about 14% of office-based prescribers.

E-prescribing systems are securely linked to the major health plans, pharmacy benefit managers, and pharmacies via the SureScripts-RxHub network. The SureScripts-RxHub network allows prescribers to retrieve patient information like medication history, eligibility, and formulary information and transmit prescriptions in a secure, real-time manner to the pharmacy of the patient's choice. The availability of this information at the point of care accounts for 70% of the safety and value associated with e-prescribing, according to a 2007 Gorman Group study (this report can be found at http://pcmanet.org/assets/pdf/GHG-PCMA%20Options%20to%20Increase%20E-prescribing%20in%20Medicare%20July%2007%20FINAL.pdf). As noted above, pharmacy connectivity for e-prescribing is approaching 100% for chain pharmacies, but lags for independent pharmacies, where only 23% are connected for e-prescribing capability.

Financial and Other Support for Adopting and Using E-Prescribing

Beginning January 1, 2009, Medicare will offer physician payment incentives of up to 2% for using e-prescribing in 2009 and 2010, with this amount declining slightly over the next three years. Payments for 2009 will be received by practices in 2010. This bonus is in addition to the separate 2% bonus which can be earned under Medicare's Physician Quality Reporting Initiative (http://www.cms.hhs.gov/pqri). Those physicians who do not adopt e-prescribing for Medicare by 2012, will start seeing their Medicare payments incrementally reduced, up to 2% annually beginning in 2014.

At the federal level, regulations released in 2006 now allow free donation of e-prescribing hardware, software, and related services to prescribers by hospitals (to members of their medical staff), by a group practice (to their physician members), and by Medicare Advantage and Medicare Part D Prescription Drug Plans. To learn more about Stark and Anti-Kickback statute compliant donations of software and hardware, read the AMA's physician guide for HIT donations, which you can download at: http://www.ama-assn.org/ama1/pub/upload/mm/472/hitdonate_physicians.pdf.
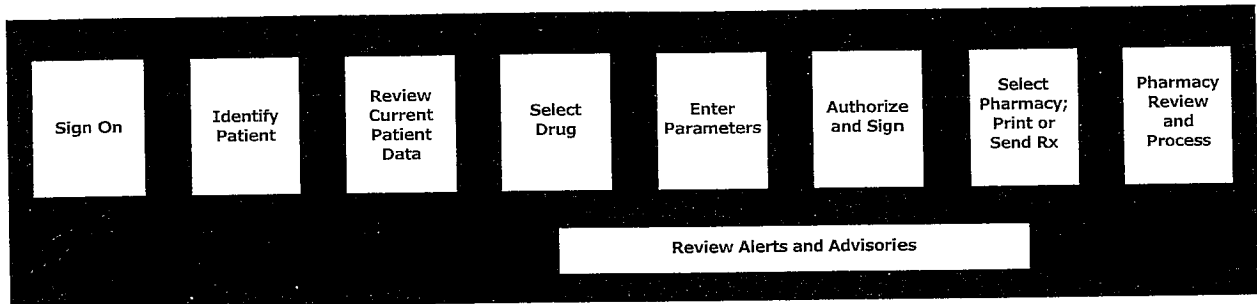
All 50 states and Washington, D.C., have cleared the path for e-prescribing—all have laws in place allowing their physicians and pharmacists to electronically exchange prescriptions and prescription information (with the exception of controlled substances). In addition, the Centers for Medicare and Medicaid Services (CMS) has provided over $100 million in Medicaid Transformation grants which are helping Medicaid programs connect to deliver formulary and pharmacy benefits information through e-prescribing and helping to encourage prescribers to adopt e-prescribing.

There are a number of national and state initiatives which are offering clinicians support for implementing e-prescribing and EHR systems. See Appendix II for more information on these programs, many of which include incentives for e-prescribing and/or EHR system adoption.

How E-Prescribing Works

Creating and managing prescriptions electronically in your practice involves several steps, as illustrated in the process map below.

Process for Creating and Managing a Prescription Electronically

Sign On	Identify Patient	Review Current Patient Data	Select Drug	Enter Parameters	Authorize and Sign	Select Pharmacy; Print or Send Rx	Pharmacy Review and Process

Review Alerts and Advisories

Signing On

A user of the system—clinician or staff—signs in by performing some sort of authentication to prove his or her identity. Typical authentication is by username and password, although other technologies such as random-number cards (SecureID™), digital certificates, or fingerprint readers are used as well. Once authenticated, the system should know the user's role and authorization level to use the prescribing system. Different types of clinicians and office staff may have different legal permissions to enter, review, or modify prescriptions.

Identifying the Patient

First, the clinician or staff identifies the patient record within the e-prescribing system. Patient records can be identified by typing in identifying information (first name, last name, date of birth, zip code) to the e-prescribing system. If the e-prescribing system is connected to the registration system, the e-prescribing system can recognize all patient records matching the day's schedule, providing a quick, simple way of accessing relevant patient records.

Selecting the Drug, Entering Parameters, Signing, Sending or Printing the Prescription

The next steps in the process correspond to reviewing the medical history, entering, and editing a prescription. E-prescribing systems should allow clinicians to perform the following functions:

1) Review patients' current medication list and medication history information:
   - Update medication history
   - Correct medication history
   - Reconcile with multiple history sources

2) Work with an existing medication:
   - View details of a medication
   - Discontinue or remove a medication
   - Change dose, etc., for a medication
   - Renew one or more medications

3) Prescribe or add new medication:
   - Search for a medication
     - From quick choices/favorites
     - By name (generic or trade)
     - By indication
     - By formulary
   - Display medications with prefilled, known, favorite, or standard dosing
   - Select medication
   - Review warnings
   - Enter SIG and other parameters
   - Automatically populate and update favorites list of drugs with prefilled known dosing based on frequency of utilization by clinician

4) Complete the prescription and authorize (electronically sign)
   - One item
   - Multiple items
   - Items created by ancillary staff, residents, or others

5) Transmit prescriptions
   - Choose print, fax, transmit options in real-time or batch mode
   - Print formats and prescription information, conforming to state regulations
   - Handle restrictions on certain medications (e.g., class II controlled substances cannot presently be e-prescribed)
   - Ensure prescription is sent to preferred patient pharmacy (identified by practice staff prior to interaction with prescriber)

SECTION II: MOVING TOWARD E-PRESCRIBING ADOPTION: WHAT YOU NEED TO KNOW AND DO TO BECOME A SUCCESSFUL E-PRESCRIBING PRACTICE

Step 1 - Assessing Your Practice Readiness

The first step when considering any technology implementation is to determine whether your practice is ready for the changes ahead. In order to be successful, your practice must agree that improvements can be made and be willing to make the necessary changes to achieve those improvements. Remember, technology is not a panacea. Information technology is simply a tool that can enable your practice to manage and access information. However, without changes in the way you work, the benefits of technology will be limited. Below are a number of considerations that will help you determine if your practice is ready for change.

Key Considerations:

Planning

- Are your practice staff and leadership open to change? Have they been willing in the past to make or accept changes to they way they work? Do they actively seek opportunities for process improvements, or have they consistently resisted change?

- Has your practice endured unsuccessful technology implementations or workflow changes in the past? If so, you should determine why those projects did not succeed. Was the practice staff engaged in the project? Was there poor communication about the project or a lack of buy-in? If your practice has a history of unsuccessful projects, particularly technology-related projects, you must first take a critical look at why those projects failed in order to avoid repeating the same mistakes.

- Are there other major projects on which your practice is currently focused? For a successful e-prescribing implementation to occur, your practice staff and leadership will need to focus on necessary decisions and changes. This means allocating extra time for planning, system selection, training, workflow integration, and implementation. If there are other major projects currently underway that will minimize the amount of time and attention your practice can spend on e-prescribing, you should consider delaying it until other initiatives have been completed.

- Do your practice leadership and staff agree that e-prescribing can lead to clinical or operational improvements? Do they have a positive or negative view of e-prescribing, or do they have any opinion at all? If the most influential members of your practice have a negative view of e-prescribing, the likelihood of success will be very low.

- Have you discussed and planned for known e-prescribing challenges such as cost; change management considerations; workflow changes; handling prescriptions for controlled substances until they are eligible for electronic submission; connectivity issues with the Internet, pharmacies, payers, PBMs, mail-order pharmacies; appropriate hardware and software selection and support services; and availability of medication history information? These challenges generally apply to most practice types, and some challenges are magnified for small or rural practices.

Communication

- Does your practice have a culture of open, honest communication? Does your practice staff feel comfortable expressing their opinions and views to leadership? When views are expressed, are they received in a constructive and respected manner? Implementing e-prescribing will impact a number of people within the practice, and it will be critical throughout the project to get their ideas and feedback.

- In the past, have decisions been effectively communicated to the practice? Are those decisions carried out by the entire practice or disregarded by some? E-prescribing implementation will require process change and standardization. If your practice has not carried out decisions made in the past, there is a risk that you will not realize the benefits of e-prescribing.

Frequently Asked Questions:

1. **Are there other tools that will help me determine my practice readiness?** There are a number of tools available that allow you to assess your practice readiness. The American Medical Association provides a readiness assessment tool (http://www.ama-assn.org/ama1/pub/upload/ mm/472/hitdonate_physicians.pdf). Texas Medical Association also offers an assessment tool (http://www.texmed.org/uploaded Files/Practice_Management/ Computers_And_Software/Are%20you%20ready%20for%20an%20EMR.doc).

2. **I am not sure if I can determine my practice readiness unless I know more about e-prescribing. Where can I find more information about what e-prescribing is and what changes it might require?** Earlier this summer the eHealth Initiative and the Center for Improving Medication Management released a comprehensive report on e-prescribing. The report describes what e-prescribing is, why it is important and the major e-prescribing initiatives. To access the report go to: http://www.ehealthinitiative.org/assets Documents/eHI_CIMM_ePrescribing_Report_6-10-08_FINAL.pdf.

3. **What should I do next if my practice is not ready?** If after reading this guide you determine your practice is not ready to successfully implement e-prescribing you should focus first on fixing those areas of concern. These issues are not insurmountable, but they will take time and effort to correct.

Additional Resources:

- **Readiness Assessment** – www.getRxconnected.com

- **Readiness Assessment, American Medical Association** - http://www.ama-assn.org/ama1/pub/upload/mm/472/hitdonate_physicians.pdf. (p. 13-15)

- **Readiness Assessment, Texas Medical Association** - http://www.texmed.org/uploadedFiles/Practice_Management/Computers_And_Software/Are%20you%20ready%20for%20an%20EMR.doc.

- **E-prescribing book** - *Electronic Prescribing for the Medical Practice: Everything You Wanted to Know But Were Afraid to Ask.* To find this book, go to http://marketplace.himss.org/acct618b/Default.aspx?tabid=57.

Step 2 - Defining Your Practice Needs

The second step when considering e-prescribing is to determine what improvements your practice hopes to gain with the use of e-prescribing technology. The benefits of e-prescribing were described in Section I of this guide, but in order to realize those benefits your practice must clearly define what your specific needs are and how e-prescribing will address those needs. If you are unclear about either of those points – what your practice needs or how e-prescribing can help – it will be very difficult to choose an appropriate project team, evaluate systems or measure whether the implementation has been successful.

Key Considerations:

Planning

- Set a clear vision for what you hope to accomplish through e-prescribing. Once you have established a vision, identify specific objectives your practice is trying to achieve with the use of e-prescribing. Your vision and related objectives should be grounded in realistic expectations with achievable, measurable results.

- Identify a project team. The project team will play an important role in adapting practice workflow to ensure that the benefits of e-prescribing are fully achieved. Therefore, the project team must be very knowledgeable about your practice's prescribing workflows and have experience in different aspects of the prescribing process. Each member of the project team should have specific roles and responsibilities so they are invested in the project.
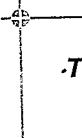
In a small practice the project team may be the entire practice staff. While your processes and structures may not be formalized, the activities are the same.

- Choose a project leader. The project leader should be extremely knowledgeable about the practice, well respected by team members, able to facilitate decision making and skilled at conflict resolution. The project leader will also assist prescribers and practice staff as they learn the new technology and workflow and help overcome barriers to adoption as they are encountered. It is not necessary that a physician serve as project leader, but if the project leader is a non-physician, it is recommended that a physician champion be identified. The physician champion would work closely with the project manager to address any unresolved conflicts and maintain the commitment of his or her peers to the success of the project.

- Plan for known e-prescribing challenges. There are general challenges that apply to most practices. Early planning for issues related to cost, change management, workflow, controlled substances, pharmacy/payer/PBM/mail-order pharmacy connectivity, hardware and software selection, and medication history and reconciliation will likely help your practice make a better decision and save time and money.

Workflow and Change Management

- Make a list of your practice's specific medication management needs. For example, do your prescribers want easy access to more complete medication lists for your patients or more robust safety checks? Do you want to reduce faxes from pharmacies for renewal requests? Do you want to understand prescription patterns or easily find patients taking a specific medication? Brainstorm with prescribers and other practice staff to determine the most significant inefficiencies and safety concerns.

- Prioritize your practice needs. When choosing an e-prescribing system your practice will have to make certain trade-offs. By prioritizing your needs before you evaluate e-prescribing systems, you will have a good idea of what features are most important to you. Needs may be prioritized by the number of staff effected, severity of risk, financial impact or effect on clinical care. When you are ready to evaluate e-prescribing systems, start with your prioritized list of needs. By comparing your needs to the features and functionalities offered by the e-prescribing system you will be able to identify the best match for your practice.

> See Appendix I for a list of common features and functions practices look for in an e-prescribing system. Use the priority column to indicate those features that are most important to your practice.

- Think through how your processes and workflow will change with e-prescribing. Map out your current prescribing workflows and then define how those workflows may change with e-prescribing. Be as detailed as possible as this will help you better understand where breakdowns occur and how you expect e-prescribing will eliminate those breakdowns.

·Technology

- In addition to your clinical and operational needs, you will also have technical needs. Again, rather than thinking in terms of what a system can do, think first about what you need. Do your prescribers need to be able to carry a device with them for easy access to clinical information, or do you simply need computers in the exam rooms? Do prescribers need to be able to access the system from outside the office (e.g., at home, while at another clinic, etc.)? Do you want data from your practice management system to populate the e-prescribing system?

- You should also consider your hardware and network needs. Is your network connection fast enough for prescribers to regularly use? Will you need a high-speed Internet connection in your office? Will you need additional computer stations, printers or a wireless network?

- Is there someone in your office currently responsible for the maintenance of information technology systems? If not, do you need someone, or will you rely on the e-prescribing vendor for ongoing support.

Communication

- Clearly describe the vision and objectives to the entire practice. Describe how they will be involved in the project, especially how their input will be collected. Be willing and ready to answer their questions in a direct, open manner.

- Involve all parts of the practice when defining needs. Each area of the practice will likely be impacted by a change to the prescribing process. Be sure you have communicated with each area to understand their particular needs, and highlight any dependencies (e.g., a change in one area's workflow impacts another area).

Frequently Asked Questions:

1. **What are the attributes of a successful practice leader?** Instilling and creating prescriber and staff behavioral change in a medical practice is difficult. It is extremely helpful when a respected physician, other clinician or practice administrator steps up as a champion and educates his or her fellow colleagues. An e-prescribing practice leader should possess the following qualities: 1) be a willing innovator, 2) somewhat technology savvy, 3) active, high volume e-prescriber, 4) strong e-prescribing advocate, 5) comfortable serving as leader and facilitator amongst his or her peers and 6) dedicated to committing time on a weekly basis for physician and staff training.

2. **What are the key considerations when redesigning my prescribing process for e-prescribing?** The following issues should be discussed at this stage. Although you might not have a final strategy for each issue at this time, you should consider strategies for each:

- How to define the role of the front desk, medical assistants, and prescribers in a redesigned prescribing process

- How to effectively implement prescriber preferences in the system

- How to provide appropriate hardware based on the prescribing roles and responsibilities of the practice

- How to communicate with patients about electronic prescribing

- How to maintain and monitor error logs

- How to monitor electronic renewal requests from the pharmacy

- How to best engage with local pharmacies in mutual problem solving

3. **What is the basic technology I need to begin e-prescribing?** Office configurations will vary depending on the e-prescribing system chosen. However, regardless of the e-prescribing system, practices must have a good Internet connection (preferably high speed) and desktop, laptop or tablets computers, hand-held PDAs, or a combination. If PDAs or tablets will be the primary technology used by prescribers, setting up a wireless network is recommended.

4. **What if my practice's needs go beyond improving the prescribing process?** Some practices decide that the prescribing process is too dependent on other clinical information to isolate. If that is the case, you should consider implementing an EHR system with e-prescribing capability. Most EHR systems have e-prescribing capability and provide more functionality than stand-alone e-prescribing systems. But EHR systems are more expensive and disruptive to the practice. Again, you have to decide what your practice is ready for and what operational and clinical needs you want to address.

Additional Resources:

- **E-prescribing case studies –** www.surescripts.com/physician/peer.aspx

- **E-prescribing information for consumers –** www.learnabouteprescriptions.com

Step 3 - Understanding Costs and Financing Options

The next step is to understand what the upfront and post-implementation costs are for e-prescribing systems and alternative financing options that might be available to your practice. There are an increasing number of federal, state, and private sources of financial aid for physicians to help encourage e-prescribing adoption.
As mentioned in Section I, federal level regulations released in 2006 now allow e-prescribing hardware and software to be donated free of charge by health insurers, hospitals, group practices and other eligible donors. Congress has also signaled its strong support of e-prescribing by providing incentives for physicians using e-prescribing. The legislation was passed in July 2008, and incentives will be available from Medicare beginning in 2009 and ending in 2013. The incentive payment will be a 2% bonus of your normal Medicare fee schedule payments. Those practices not e-prescribing by 2012 will see a reduction in Medicare payments.

> For more information on the relaxation of Stark and Anti-Kickback, go to www.ama-assn.org/go/hit.
>
> For more information on the Medicare e-prescribing program, go to www.cms.hhs.gov/eprescribing.

Key Considerations:

Planning

- Identify a member(s) of the project team to research the costs and potential subsidies or reimbursement programs available to your practice. Contact the health plans in your area to inquire about initiatives they may sponsor or pay-for-performance programs that help practices acquire e-prescribing systems.

- Identify any existing national and state initiatives for which the practice may qualify. Many organizations – including state governments, payer organizations, medical associations and e-prescribing vendors – have developed special programs to encourage prescribers to adopt e-prescribing technology. A list of some of those programs can be found in Appendix II.

- Calculate your practice's projected reimbursement under the new Medicare incentive legislation and research pay-for-performance programs for which your practice is eligible to participate.

Technology

- If you are considering both stand-alone e-prescribing systems and EHR systems, document price differences between a stand-alone e-prescribing system and an EHR system with e-prescribing functionality. Include all hardware (desktop, laptop, PDA, servers, printers), software, interfaces and networking costs (i.e., Internet connectivity, wireless network, integrating practice management system with e-prescribing or EHR). Also include in the costs for a stand-alone system, the projected costs and implementation challenges of later moving to an EHR system (i.e., data transfer, technical infrastructure changes).

Frequently Asked Questions:

1. **How much does e-prescribing cost?** Costs vary depending on which kind of hardware and software (EHR system versus a stand-alone e-prescribing system) a practice chooses. Stand-alone e-prescribing applications range from free to approximately $2,500 per year per prescriber. Be sure to look for local or state initiatives that subsidize the cost of e-prescribing systems. There may be additional fees to integrate patient demographic information from your practice management system into the e-prescribing application; however, the alternative means you will need to enter each patient into the system as you prescribe for them, which can be time consuming and may be a barrier to using the system.

   As mentioned in Section I, EHR systems offer more comprehensive functionalities, but are more costly, complex and time consuming to implement. According to the Congressional Budget Office, office-based EHR systems are about $25,000 to $45,000 per physician. Estimated annual costs to operate and maintain an EHR system (e.g., software licensing fees, technical support, and updating and replacing used equipment), range from $3,000 to $9,000 per physician per year. Be sure to ask vendors specific questions about any incremental fees related to e-prescribing functionality as well as training.

   These figures do not include initial costs for the hardware required to support either an e-prescribing or EHR system, temporary decreases in productivity resulting from training or workflow redesign, practice management interfaces, customization, maintenance, upgrades, or data conversation. Whether you choose a stand-alone e-prescribing application or an EHR system with integrated e-prescribing, cost is only one part of the equation. You should compare the cost – both direct and indirect, start-up and ongoing – with the expected benefits – such as improved efficiency and productivity, decreased administrative expenses and staff utilization – to fully understand the value of e-prescribing to your practice.

2. **Are there transaction fees for e-prescribing?** Pharmacies pay transaction fees based on the number of electronic prescriptions and electronic prescription renewals received, and payers/PBMs pay transaction fees to deliver formulary and pharmacy benefits information. The only time your practice would incur transaction fees for e-prescribing is if the vendor you select charges your practice a transaction fee. Most vendors do not charge practices a transaction fee, but be sure to ask your potential vendors about this during system selection.

3. **Are there subsidy programs available to help with e-prescribing costs?** Yes. There are a number of e-prescribing and EHR initiatives available at the national and state level. Information about some of these programs is provided in Appendix II.

4. **Does e-prescribing cost patients more money?** Patients pay the same amount in the same way for electronic prescriptions as they do for traditional paper ones. With e-prescribing, however, prescribers will likely have information about the patient's formulary at the time of prescribing, which may allow prescribers to prescribe a medication with a lower co-pay or cost to the patient if paying out of pocket.

- **Certification Commission on Health Information Technology
  Incentive Index -** http://ehrdecisions.com/incentive-programs/

Step 4 - Selecting a System

There are many e-prescribing systems to choose from and evaluating them may seem daunting. However, by this point you have identified your practice needs and understand associated costs. By comparing your practice needs with key e-prescribing system capabilities and integration features, your practice is more likely to choose an e-prescribing system that will be a success. Use the Buyer's Guide checklist in Appendix I when comparing different vendor offerings.

Key Considerations:

Planning

- Involve the entire project team in system selection. Define specific evaluation criteria so that multiple products can be easily compared. Facilitate open discussion among team members about the pros and cons of each product and their rationale for scoring. If you are concerned that some members of the evaluation team will not feel comfortable openly sharing their perspectives, the scorecards can be confidential and known only to the project leader.

- Develop your own test scripts or scenarios reflecting your practice's common workflows, and ask each vendor to demonstrate how their product would work in those scenarios. This will show how the systems would be used in your practice environment and focus the vendor on what features and functions are most important to you. It will also allow you to compare features and usability across systems.

- Contact other practices in your area that currently use the products you are evaluating. Ask what unexpected challenges they have faced, how responsive the vendor has been, and why they chose that product.

Workflow and Change Management

- Evaluate usability features of each software vendor such as:

    – Minimal keystrokes to write, renew, and send prescriptions

    – Easy patient lookup process

    – Connection with current patient management systems to integrate patient demographics into the e-prescribing application quickly and easily

    – Access to medication history information—with multiple history sources reconciled to a single view

    – Ability to renew multiple prescriptions for a patient at once

    – Favorite medication list feature

    – Easy medication search (including trade names)

    – Pre-filled default fields

    – Ability to do complex SIGs through templates (like sliding scales, tapers, etc.)

    – Ability to order supplies like syringes

    – Incorporation of alternative and non-prescribed medications in the medication list

    – Clinical decision support warnings such as drug-drug and drug-allergy alerts that are advised but not forced. Drug-lab, drug-problem checking are also desirable functions.

    – Inclusion of reasons for prescribing (match to problem list or diagnosis)

    – Easy signing and cosigning

    – Easy pharmacy selection

    – Easy and most efficient output

    – Ability to receive delivery confirmation or failure notice once prescription reaches pharmacy

    – Ability to handle callbacks/renewal requests (from patient or pharmacy)

- Make sure you clearly understand what training is offered by the vendor. Will the training be on-site? How many days will it be? Will the training be hands on and will you be able to ask the trainer questions? Will there be follow up training sessions or will your practice have access to the trainer over the first few months of implementation? Will you be able to schedule training during non-business hours? Your staff will not be able to learn all the features of the system in one session, so be sure that the training plan is sufficient. Be sure to ask specifically about training costs.

Technology

- Ensure that the hardware (desktop, laptop, PDA) required by the system supports your practice's desired workflow. Determine that devices are both efficient and secure. They must allow rapid synchronization to other electronic systems in the office, as well as communication with printers and other devices or networks.

- Select Internet connectivity with a redundant Internet connection backup in place. Be sure access is available wherever you hope to use the system, including other office sites, at home, at the hospital, etc.

Frequently Asked Questions:

1. **Is there a certification system for e-prescribing systems?** Yes. E-prescribing applications and EHR systems with e-prescribing are certified by SureScripts-Rx Hub – the infrastructure that technology vendors, pharmacies, and payers/PBMs connect to in order to exchange medication information electronically according to industry standards. The current certification is based on compliance with industry standards, specifically the NCPDP Script Standard. A complete list of SureScripts-RxHub certified products can be found at http://www.surescripts.com/certified. This list shows the functionality and connectivity of e-prescribing systems. If your practice is looking for an EHR system with integrated e-prescribing functionality, the Certification Commission for Heath Information Technology (CCHIT) certifies EHR systems based on a large number of functional criteria, including e-prescribing capability. CCHIT has plans underway to certify e-prescribing systems. For more information on CCHIT, go to www.cchit.org.

2. **Are there specific questions I should ask a potential e-prescribing system vendor?** Yes, ask questions such as: 1) What is the cost? 2) What do I need to purchase? 3) What are the monthly maintenance fees? 4) What type of training is provided? 5) Will your system be able to access demographic information from my practice management system? 6) Does your system allow you to manage both new prescriptions and renewal authorizations electronically? 7) What is the support process, and how long does it typically take for issues to be addressed? For a complete Buyer's Guide, see Appendix I.

Additional Resources:

- **Vendor features list** – www.surescripts.com/certified
- **E-prescribing selection assessment tool** – www.himss.org/content/files/App_C.pdf
- **E-prescribing book -** *Electronic Prescribing for the Medical Practice: Everything You Wanted to Know But Were Afraid to Ask.* To find this book, go to http://marketplace.himss.org/acct618b/Default.aspx?tabid=57.

Step 5 - Deployment

The final step is deployment. Implementing e-prescribing and ensuring the system's proper use will require commitment and effort. It will take time to adapt to new workflows and to use the system effectively. The following questions and checklist are intended to help your practice through the early stages of deployment and minimize productivity loss.

Key Considerations:

Planning

- Commit staff time during implementation for training and workflow integration. You may want to decrease the patient load for the first few days of implementation to ensure that staff has time to work with the new system.

- Ensure that all affected members of the practice receive appropriate training. On-site training is most effective as it allows users to learn the system in their working environment. In preparation for training, think about specific questions that may not be covered. Sample questions may include:
    - How do I search for certain medications within my database?
    - What do I do when I do not find a particular medication in the database?
    - Can I create customized SIGs?
    - How do I handle pediatric dosing and SIGs?
    - How do I write prescriptions for medical supplies?
    - How do I write for tapering dose SIGs or write prescriptions that have SIGs that don't fit in the designated SIG section?
    - What do I do when I want to write a prescription for a compound medication?
    - Why can't I find this particular pharmacy in my system?
    - Why do I get this error when I write this particular prescription?
    - How can I write a prescription from the patient prescription history screen?

- Pace yourself. Do not attempt to learn everything at once. It is difficult to learn the all the details of the system in one training session. An incremental approach to training over several days works better. It is also a good idea to schedule a few additional training sessions with your trainer over the next few months. You will have many more questions after you have gained practical experience with the system.

- Ask your vendor if they provide access to such learning material as webinars, online tutorials or implementation guides, and make full use of all available resources to maximize your e-prescribing experience.

> Full EHR system implementation requires significant practice buy-in, funding and technological readiness, in addition to more workflow change than is necessary for a stand-alone e-prescribing system installation. Smaller practices may find the latter an easier first step in automating their practice.

. Technology

- Keep your software vendor informed about any problems. The project leader, or a designee, should be in contact with your vendor on a regular basis to fix any technical problems or usability issues. By keeping your vendor aware of issues that arise, you ensure that problems can be fixed quickly and help eliminate future issues before they occur. Be sure that everyone who uses the e-prescribing system in the practice is aware of and follows the support process provided by the vendor.

- Log support cases with the technology provider. If the issue is related to a pharmacy or network issue rather than an application issue, the technology provider should notify SureScripts-RxHub for resolution. Common issues that should be reported include when a practice is informed by a pharmacist or patient that their prescription or prescription renewal is not there (commonly referred to as a mishandled prescription); and faxed renewals from pharmacies that are electronically enabled. It is important to report adequate detail on these issues and contact your vendor immediately.

- Set default routing to electronically send prescriptions to the pharmacy rather than faxing them. Systems that provide the option for prescribers to decide whether to fax, print, or electronically send prescriptions tend to result in under use of electronic transmission. However, clinicians should always have the ability to print the prescription or a receipt of the prescription order for the patient.

- Utilize electronic prescription renewal functionality as this increases efficiency and improves patient service when they are able to get their prescriptions renewed more quickly. Electronic renewals can also encourage more staff involvement in the prescribing process and lead to stronger commitment to e-prescribing. Automating the process to authorize prescription renewals as part of e-prescribing is a key benefit for the practice and a key driver of utilization. Instructing patients to request refills through their pharmacy instead of calling the physician office can decrease phone calls to the office and increase the efficiency of handling the requests when they come electronically directly from the pharmacy.

- Integrate patient demographic information from the practice management system in advance of e-prescribing implementation. Not having the practice patient demo graphic information loaded in the e-prescribing application system during a patient visit can be a major source of dissatisfaction for both prescribers and practice staff. Also be sure that the system you plan to implement can update new patients and changes in demographic information from your practice management system regularly.

- Designate a prescriber or staff person to retrieve and manage responses for renewal authorization requests that are sent electronically from pharmacies. This person can help to successfully implement the electronic renewal process by checking your prescribing system each day, or several times a day, for electronic requests. Consider distributing patient educational materials on e-prescribing that instruct them to contact their pharmacy first for refill requests or displaying signage in the office to remind patients of the best process.

- Make sure you know how to select your patient's pharmacy of choice using your e-prescribing application. You should be familiar with how to select both the name and location of your patient's pharmacy of choice and how pharmacy information is displayed and updated in your prescribing application. Once you start using your application, make it a practice to ask your patients to select or confirm their pharmacy of choice when they check in for their visit. You or your staff can then add the pharmacies' names to the patients' electronic records and speed the process of preparing their prescriptions using your e-prescribing application. As an added step, you may wish to build a "favorites" list of pharmacies within your application, using your patients' favorite locations, for quick selection during the check-in process.

- Respond to electronic renewal requests as soon as possible, and always within 24 hours on business days. If pharmacies do not see a response within that time frame, they may send duplicate renewal authorization requests. This may also happen if the patient is waiting in the pharmacy to pick up a renewed prescription that has not yet been authorized. It helps to designate someone to manage the electronic refill response process.

- Avoid queuing or "batching" prescriptions before sending them to pharmacies electronically. Sending prescriptions to pharmacies as soon as possible after they are prepared ensures that the pharmacy has adequate time to receive the prescription before a patient arrives to pick it up. Otherwise, the practice may receive unnecessary calls from pharmacies asking where the prescription is, further delaying the patient's receipt of the medication.

- Follow DEA regulations by refraining from electronic transmission of prescriptions for controlled substances until these regulations are changed to allow electronic transmission. Prescriptions for Schedule II drugs can never be sent electronically. Hand-signed hard copies of prescriptions for Schedule III through V drugs can be sent using manual fax. Neither computer-generated faxes containing electronic signatures nor totally electronic prescriptions for controlled substances can be sent to pharmacies at this time.

Communications

- Inform local pharmacies that you are getting ready to exchange prescription information electronically. When your e-prescribing application is set up at your practice, your vendor should inform pharmacies in your area that you will be prescribing electronically. Your ongoing use of your prescribing application will then reinforce this notice and will allow pharmacies to start sending refill requests to your prescribing application—if you are set up to manage these requests electronically.

  Independent pharmacies, especially, do appreciate hearing directly from practices and clinics that are planning to e-prescribe. This can also help encourage those who are not yet able to manage e-prescriptions to get connected. A letter template has been developed to help you make this announcement, which can be downloaded at: http://www.rxsuccess.com/files/pdf/MD%20to%20Pharmacy%20 Outreach%200508.pdf.

- Communicate with patients about electronic prescribing and its benefits and remind them to call the pharmacy rather than the practice when they need their prescriptions renewed.

Frequently Asked Questions:

1. **How do I know which local pharmacies accept electronic prescriptions?** A quick resource to find this information is www.rxsuccess.com. Simply click on the "Find your connected pharmacy" tab to find the list of pharmacies in your state or zip code that are enabled to receive electronic prescriptions and send electronic renewal requests to your practice. You still should contact the pharmacies in your area directly to notify them when your practice will be e-prescribing and confirm that they have actually started using e-prescribing and are prepared to accept the prescriptions.

2. **How will I know if pharmacies are properly loaded in my system?** It is best to provide your vendor with a comprehensive list of pharmacies that your patients frequently use. The vendor can then match this list with the pharmacy records from the Pharmacy Health Information Exchange while loading pharmacy information in your application. This will help ensure that your frequently used pharmacies are appropriately matched to the master pharmacy file from the beginning and thus enabled for electronic prescriptions. If your practice application allows you to create customized pharmacy records (customized name, address or phone and fax number) then it is also important to ensure that the application system matches such records with the master pharmacy list provided by the Pharmacy Health Information Exchange.

3. **How can I prepare for training?** Personalized one-on-one training using a variety of common scenarios seems to work best for most prescribers. It is important to ask detailed questions during your training sessions, including:

   - What happens if the patient is not matched in the system when a pharmacy sends a renewal requests?
   - Can I cover for my colleagues when they are on leave and under whose name will the prescriptions be sent to the pharmacy?
   - How does the system handle controlled substance prescriptions and pharmacy renewal requests for controlled substances?
   - How do I write prescriptions to the pharmacy when a patient calls in a request via phone?
   - How do I know whether the prescription was successfully sent to the pharmacy?
   - How do I handle mail order prescription writing?
   - How do I create my favorite medication list?
   - How do I search pharmacies within the practice database?

4. May I work offline using my e-prescribing system? Some e-prescribing programs allow access offline, which would enable prescribers to prepare multiple scripts and then transmit then when they have Internet access again. However, queuing or "batching" prescriptions before sending them to pharmacies electronically is not recommended. Sending prescriptions to pharmacies as soon as possible after they are prepared ensures that the pharmacy has adequate time to receive the prescription before a patient arrives to pick it up.

5. Will the pharmacy send me electronic renewal requests? Pharmacies will start sending e-refills once individual prescribers send five new prescriptions electronically via the Pharmacy Health Information Exchange. This is to help ensure that your practice has been trained on your e-prescribing or EHR system and is ready to receive and respond to refill requests electronically.

6. Can I e-prescribe controlled substances? Prescriptions for Schedule II drugs can never be sent electronically or by fax. Hand-signed hard copies of prescriptions for Schedule III through V drugs can be sent using manual fax technologies. Neither computer-generated faxes containing electronic signatures nor totally electronic prescriptions for controlled substances can be sent to pharmacies at this time. Some pharmacies will continue to send refill requests for controlled substances by fax.

7. How do I communicate e-prescribing to my patients? Communicating with patients regarding e-prescribing and its benefits and implications is important. Some patients may express initial reluctance in response to a new system; prescribers can make patients more comfortable by explaining how e-prescribing works and what its benefits to patients, providers, and pharmacies.

In the initial phases it is important for you and your practice staff to educate and reinforce the benefits of e-prescribing with your patients. Talking points include:

- **Fast** - E-prescribing allows you to electronically send prescriptions directly to the patient's choice of pharmacy. The prescription travels from your computer to the pharmacy's computer before the patient leaves the exam room, giving their prescription a "head start."

- **Convenient** – The patient no longer has to make an additional trip to the pharmacy to drop off their prescriptions.

- **Safe and Secure** - Prescription information is not sent over the open Internet and is not sent via an e-mail. E-prescriptions are sent electronically through a private, secure, and closed network – the Pharmacy Health Information Exchange®.

- **Legible** – The staff in the pharmacy no longer has to spend time interpreting your handwriting.

- **Informed** – Availability of formulary information from health plans allows choice of medications that are more affordable and e-prescribing allows drug-drug interaction checking and allergy-drug interaction checking for safer choices.

Additional Resources:

- http://www.rxsuccess.com/
- http://www.surescripts.com/SureScripts/myth-reality.aspx

APPENDIX I: BUYER'S GUIDE

Once you have decided on the type of system for your practice, you will want to start contacting system providers to find out more about their specific products. The following Buyer's Guide will help you compare the features of different systems. In order to qualify for Medicare's e-prescribing bonus that begins in 2009, be sure the system you select meets all Medicare Part D e-prescribing standards which go into effect on April 1, 2009— these standards are listed on the Centers for Medicare and Medicaid Services website at: http://www.cms.hhs.gov/eprescribing.

Electronic Prescribing System Buyer's Guide						
Category	Feature or Function	Question to Ask Vendor	System A	System B	System C	Priority (High, Med., Low)
Functionality	Refill Authorization	Will the system enable me or my staff to receive refill requests from pharmacies directly on my computer instead of by fax or phone and send back approvals or denials electronically with a few key strokes?				
	New Prescriptions	Can I send a new prescription directly to the pharmacist's computer through my PDA, Desktop, Laptop or Tablet PC instead of to their fax machine?				
	Two-way Communication	Is the system enabled for two-way electronic communications with pharmacies or just one-way fax transmission of new prescription information?				
	Reporting	Does the system include reporting capability about prescription history for the patient and practice?				
	User Tools	Does the system provide aids such as favorites-lists or chart-labels to aid system and practice workflow?				
	Drug Interaction Checking	Does the system provide alerts for drug to drug, drug to allergy and other checks for patient safety?				
	Drug Benefits Displays	Does the system display drug benefits information related to patient's drug coverage to help manage patient cost?				
	Prescription History	Does the system display prescription history from retail pharmacy and/or PBM data sources (across providers)?				
Related Functions (EHR Systems)	Modules	Does the system provide one or more related modules, such as lab results or charge capture?				
	Modular EHR	Does the vendor provide a comprehensive EHR that can be implemented in stages beginning with electronic prescribing?				

Electronic Prescribing System Buyer's Guide							
Category	Feature or Function	Question to Ask Vendor	System A	System B	System C	Priority (High, Med., Low)	
Hardware Architecture	Mobile	Can the system run on a device such as a PDA, and does it provide a method of synchronization, either wirelessly or through a cradle?					
	Desktop	Does the system provide applications that run on a desktop, requiring just an internet connection, or additional software?					
	Remote Computing	Does the system provide access when prescribers are away from the office?					
Services	Initial Training	Does the vendor provide training for the physicians and staff in the use of the application? Is the training on-site or remote?					
	Ongoing Support	Does the vendor provide ongoing support and customer service to assist after implementation?					
	System Interfaces	Does the vendor provide the ability to retrieve demographic information from the billing system?					
	Updates	Does the vendor send periodic updates to the system for ongoing improvements and enhancements?					
Standards	Regulatory Compliance	Does the system satisfy all CMS Part D e-prescribing standards required as of April 1, 2009? Visit http://www.cms.hhs.gov/eprescribing/ to download the standards.					
Costs	Hardware	What are the costs of all recommended hardware including networking equipment?					
	Software and Services	What are the one-time and ongoing costs for the software and any training and interfacing services?					
	Special Offers	Are there any special offers such as free trials, rebates or discounts?					

APPENDIX II: NATIONAL AND STATE E-PRESCRIBING INITIATIVES

The below table is intended to summarize current e-prescribing initiatives. This information may change. For an updated reference of national and state incentive programs related to the adoption of EHR systems—which incorporate e-prescribing functionality—see the Certification Commission for Health Information Technology's (CCHIT) Incentive Index, available at http://ehrdecisions.com/incentive-programs/. This website also contains guidance for physicians on the adoption of EHRs for their practice.

National Initiatives

Company	Contact Info	Description
American e-Prescribing Initiative	www.rxnt.com/AMEI/enroll.asp 800-943-7968	Eligible participants include new RxNT e-prescriber groups enrolling more than 100 licensed prescribers at the same time.
AthenaHealth	www.athenahealth.com 888-652-8200	Eligible participants include existing purchasers of Athena Clinicals products.
National ePrescribing Patient Safety Initiative (NEPSI)	www.nationalerx.com	NEPSI makes secure, easy-to-use e-prescribing software available to all physicians and medication prescribers in America for free.
WellPoint	www.wellpoint.com	Provides a free Web-enabled smart phone with e-prescribing access and WellPoint corporate discounts for service fee extended to individual physicians and groups in select markets.

State Initiatives

State	Sponsor	Contact Info	Description
Arizona Health-e Connection	Multi-stakeholder collaborative	www.azhec.org	Providing education for providers, payers, and consumers on e-prescribing, health information technology, and health information exchange.
Alabama InfoSolutions e-prescribing Program	Blue Cross and Blue Shield of Alabama	www.Infosolutions.net 205-220-5900	Physicians who agree to utilize InfoSolutions as part of their participation in the Alabama Medicaid Patient 1st Program are eligible to receive $300 reimbursement toward the cost of the PDA if 1,000 patients are accessed in the first six months of use.

State	Sponsor	Contact Info	Description
California *L.A. Care Program*	Anthem Blue Cross, Blue Shield of California and Medco Health, WellPoint		The L.A. Care Program reimburses eligible physicians up to $3,000 for e-prescribing. Physicians must write a minimum of 80 electronic prescriptions per month for three consecutive months to qualify for reimbursement.
Colorado *QHN Prescription Management*	Quality of Health Network	www. Infosolutions.net 970-248-0033	Eligible participants include any Colorado prescriber.
Connecticut *Connecticut Health Information Exchange and E-Prescribing Initiative*	Aetna and Zix	Edmund Pezalla, MD www.aetna.com 860-273-0123	Aetna and Zix have expanded the e-prescribing Initiative to New York, offering hand-held devices to participating physicians.
Delaware	Blue Cross Blue Shield/DrFirst	Blue Cross Blue Shield of Delaware 302-421-3000	BCBSD's pilot program provides physicians with personal digital assistants and DrFirst's Rcopia™ software to allow them to access up to 10 years of their patients' medication histories, including active medications, allergy information and diagnosis information.
Florida *ePrescribe Florida*	Florida Medicaid, Gold Standard	www. empowerx.com/ florida 1-800-375-0943 empowerx@id-health. com www. eprescribeflorida.com	Provides e-prescribing to providers through a secure Web portal and personal digital assistants. Includes claims-based prescription histories for fee-for-service beneficiaries, information about the State's Medicaid drug formulary, and a tool to alert providers about potential drug interactions. Fosters education and implementation efforts to accelerate physician adoption and cooperation among prescribing constituents.

State	Sponsor	Contact Info	Description
Idaho *The Idaho Physicians Network* *Idaho e-Prescribing Initiative*	Primary Health Inc., a Boise insurance com-pany, DrFirst RxNT	Charles Petrock, Idaho Physicians Network cpetrock@ipnmd 208-333-1525 www.rxnt.com 800-943-7968	This pilot program is the first sponsored e-prescribing project in the state. This program offers incentives to new RxNT e-prescribers licensed in Idaho.
Illinois *Illinois e-Prescribing Collaborative* *Illinois e-Prescribing Initiative*	Blue Cross and Blue Shield of Illinois. RxNT	Blue Cross and Blue Shield of Illinois (312) 653-6000 www.rxnt.com 800-943-7968	Initial costs for e-prescribing implementation for 500 physicians will be funded. This program offers incentives to new RxNT e-prescribers licensed in Illinois.
Indiana *Indianapolis Medical Society - Preferred Physician Program*	Indianapolis Medical Society, iSALUS	www.imsonline.org or simonlee@isalushealthcare.com	Provides IMS member physicians with one year of free access to an online electronic medical records system which includes e-prescribing.
Louisiana *Louisiana e-Prescribing Initiative*	Blue Cross Blue Shield RxNT	EDI – Electronic Services Clearinghouse Support 225-291-4334 www.rxnt.com (800) 943-7968	A group of 500 Louisiana physicians will be chosen to test a new e-prescribing service designed to reduce errors and increase patient safety.
Maine *HealthInfoNet*	Anthem Blue Cross and Blue Shield of Maine	Operations Center 207-822-7000	Will equip about 500 Augusta-area physicians with e-prescribing technology that will link to the electronic medical records of their Anthem-enrolled patients.

State	Sponsor	Contact Info	Description
Massachusetts *Massachusetts eRx Collaborative*	Blue Cross Blue Shield of Mass. and Tufts Health Plan, DrFirst, ZixCorp	Contact the eRx Collaborative technology partners: DrFirst: 888-271-9898 ext 3 ZixCorp: 800-822-0675 Blue Shield of Massachusetts HMO Blue, Inc. 800-262-BLUE (2583)	Blue Cross Blue Shield of Massachusetts (BCBSMA) has developed a pay-for-performance program for participating primary care providers. Through the program, eligible e-prescribers can receive sponsorship which includes: hand-held device loaded with e-prescribing software, one year license fee and support, 6 months of Internet connectivity where applicable, deployment (including training & one time patient data download where feasible), and access to a browser version of the software from any PC with Internet connectivity.
Michigan *Southeast Michigan e-Prescribing Initiative (SEMI)*	GM, Ford Daimler-Chrysler UAW, BCBS of Mich., Henry Ford Med. Group, Medco Health Solutions, CVS/Caremark, Surescripts-RxHub	800-722-8979	Launched in 2005, the initiative encourages physicians to write prescriptions on a personal computer or wireless device and send them directly to the pharmacy for filling.
Minnesota *Government Health IT*	Minnesota eHealth Collaborative	Anne A. Armstrong, President and Group Publisher 703-876-5041 aarmstrong@ 1105govinfo.com	By 2009, the state employee health plan will require all in-network pharmacies to accept e-prescribing. By 2011, all network providers must e-prescribe. Failure to meet these deadlines could mean removal from the network. Physicians who do not comply with the 2011 e-prescribing deadline will not be reimbursed for treating state employees.
Mississippi	Mississippi Medicaid, Gold Standard	www.empowerx.com/ mississippi.html 800-375-0943 empowerx@id-health. com	Provides e-prescribing to providers through a secure Web portal and free personal digital assistants.

State	Sponsor	Contact Info	Description
Nevada *Sierra Health Services and Southwest Medical Associates*	Sierra Health Services and Allscripts	w3_hpnsd_shl@ sierrahealth.com Allscripts: 800-654-0889	Under the program, physicians who are members of the Nevada State Medical Association can receive Allscripts' e-prescribing software at no cost for two years, while nonmember physicians can receive the software at no cost but must pay a $20 monthly fee to use it. All physicians must pay for their own hardware, including computers and monitors.
New Jersey *Aetna, Horizon BCBSNJ's E-Prescribe Program*	Horizon Blue Cross Blue Shield of New Jersey (Horizon BCBSNJ)	Please contact your Aetna Account Executive www. HorizonBlue. com/eprescribe 800-355-BLUE (2583)	Sponsors e-prescribing for select network physicians.
New Mexico *New Mexico Prescription Improvement Coalition*	Blue Cross Blue Shield, Molina, United, Lovelace, Presbyterian, New Mexico HSD, Medicare AD	www.nmmra.org 505-998-9765	A statewide, physician-centric, multi-payor, self-sustaining, electronic prescribing model is currently in the pilot phase. To assure adoption, all major health plans are participating in the program. Health plans' formularies will be loaded into the e-prescribing applications for ease of physician access. Implementation costs of this pilot are being funded by participating health plans, based on New Mexico member enrollment for each plan. More than 120 physicians are participating in this pilot to date.
New York *NYC Dept of Health and Mental Hygiene, Electronic Health Records Initiative* *New York State, Greater Rochester Area – Elysium Prescription Management*	New York City GRRHIO	www.nyc. gov/pcip or 866-888-MY-CW. www.grrhio.org 877-865-7446	Eligible participants include primary care providers practicing in medically underserved areas of New York City. Provides incentives for prescribing members of the Rochester Regional Health Information Organization (RHIO).

State	Sponsor	Contact Info	Description
North Carolina *North Carolina e-Prescribing Initiative*	BlueCross BlueShield of North Carolina	www.rxnt.com 800-943-7968	BCBSNC is offering a one-time $1,000 incentive to network providers who want to participate in the e-prescribing initiative. To qualify for the incentive, providers must be registered with a certified e-prescribing vendor and must access medication history for a minimum of 20 patients in the fourth quarter of 2008.
Ohio *Cincinnati Ohio e-Prescribing Initatives*	Anthem Blue Cross and Blue Shield RxNT	800-442-1832 www.rxnt.com 800-943-7968	This e-prescribing pilot will equip 100 physicians in Dayton and Warren/Youngstown with computer equipment and free use of an online tool that provides instant access to current patient formulary information and medication history. Financial incentives for participating physicians are provided during the pilot. Incentives are also available to all physicians who e-prescribe and are eligible for Anthem's pay-for-performance programs in the above areas. Available to RxNT e-prescribers that are licensed to prescribe medications in Cincinnati, Ohio only.
Pennsylvania *Highmark e-Prescribing and eHealth Initiative*		412-544-7000	Highmark's e-Prescribing/eHealth Initiative, is contributing $29 million to help physicians acquire e-prescribing technology for their practices. Highmark will pay up to 75 percent of the cost for a physician's office to acquire, install and implement eligible e-prescribing systems, up to a maximum $7,000 per physician.
Rhode Island *Quality Counts*	BlueCross BlueShield of Rhode Island	800-204-0028	The BlueCross BlueShield of Rhode Island "Quality Counts" incentive program encourages physicians to prescribe electronically.
Tennessee *Shared Health ePrescribe*	BlueCross BlueShield of Tennessee	Fred Flint 423-535-8258	E-prescribing is currently available to all prescribing providers participating in the State's EHR initiative. Physicians receive the equipment, training and support for free.

APPENDIX III: ELECTRONIC PRESCRIBING ISSUES

Early adopters of e-prescribing have encountered technical and workflow issues. This table delineates those issues, explains why they may be happening and what you can do about it.

Issue	Why it happens and what to do about it
Multiple requests for renewal	Practices may receive phone calls from patients and pharmacies about the same renewal requests in addition to receiving electronic renewal requests and fax renewal requests. Part of this can be improved by educating patients to call the pharmacies rather than the practice for prescription renewals. It also helps to respond timely to electronic requests so the pharmacy does not call or fax in order to get a response when the patient is waiting for the prescription. Duplicate fax renewal requests may occur if the prescriber is not properly matched in the pharmacy system. If you receive fax renewals from pharmacies that are connected, log support cases with your vendor so they can work through SureScripts-RxHub and they in turn with the pharmacies to ensure the prescribers are fully matched in the pharmacy systems. This should lead to a reduction in fax renewals.
Pharmacies not checking their e-prescribing system	In some cases, pharmacies think that they have not received a prescription, thus requiring the patient to call the physician's office. When this occurs physicians became concerned that the e-prescribing system is not functioning correctly. Some practices became so concerned that they send duplicate prescriptions, one via e-prescribing and one via fax or hard copy, creating extra work on their part and confusion at the pharmacy. The confusion at the pharmacy can cause patients to prefer a paper prescription over an electronic one. This may occur if the pharmacy staff has to look in a different part of their computer system for an electronic prescription or go outside of their regular workflow to find and process an electronic prescription.

To help with the situation, practices can educate their patients to remind the pharmacies to check their e-prescribing system. In recent years, many pharmacies have made improvements in their software so that e-prescribing is more integrated with the entire workflow. It is more obvious that an e-prescription has been received and no longer requires going to a different queue to check and requires minimal re-keying of information. Given the low volume of e-prescriptions at this time compared with the overall prescription volume, there still may be training issues in the pharmacy.

If you experience instances where a patient shows up in their pharmacy and is told the prescription is not there, you should log a support case with your vendor, and they should pass the information to SureScripts-RxHub who will in turn provide the information to the pharmacies who will retrain the staff in the pharmacy. There is also a possibility that this occurs if there is confusion about which pharmacy the patient wanted to go to and which pharmacy the prescription was actually sent to, so pharmacy selection in the e-prescribing or EHR system is critical. |

Issue	Why it happens and what to do about it
Pharmacies sending renewal requests in multiple manners, i.e., fax and e-Rx, causing confusion in the practice about which request to act on and lack of confidence that the system works	If the pharmacy is connected for e-prescribing, they should be sending renewal requests electronically. Automating renewal authorizations is a critical benefit of e-prescribing. Fax renewal requests may occur if the prescriber is not properly matched in the pharmacy system. If you receive fax renewals from pharmacies that are connected, log support cases with your vendor so they can work through SureScripts-RxHub and they in turn with pharmacies to ensure the prescribers are fully matched in the pharmacy systems. This should lead to a reduction in fax renewals and an improved e-prescribing experience. This is an easy problem to solve when the vendor, SureScripts-RxHub infrastructure, and pharmacies are made aware of the problem.
Patients refusing e-prescribing as a result of a bad experience or because they do not know which pharmacy they will use	You should always have the option to print prescriptions for patients who prefer paper over electronic. It is difficult to get trust and confidence back after there is a bad experience. Patient education is important, and the practice should help patients understand that e-prescribing is safer, more efficient, convenient, and reliable. They should also be encouraged to remember which pharmacy they typically use when they come in for an office visit and are likely to need a prescription.
Physicians questioning the advantage of e-prescribing over computer-generated faxing and feel it creates more work and potentially additional costs	The disadvantage of EHRs that generate fax prescriptions to the pharmacies is that typically you cannot automate the renewal authorization process, which is a time saver in the practice. Effective January 1, 2009, those computer generated fax prescriptions will no longer be in compliance with Medicare Part D. Depending on the size of the practice and the practice workflow and roles and responsibilities for medication management, some tasks such as documentation fall increasingly on the physician. Hopefully the practice has a strong enough belief that the EHR or e-prescribing technology will result in higher quality care, better and more accessible documentation, and an improved medication management process.

APPENDIX IV: ELECTRONIC PRESCRIBING STATEMENT OF PRINCIPLES

The Steering Group for the June 2008 report, "Electronic Prescribing: Becoming Mainstream Practice", suggests the following principles that represent consensus among diverse stakeholders. These principles should help guide ethical, technical, policy, and financial developments in this field, and stakeholders are encouraged to utilize them as they develop their strategic and tactical initiatives on electronic prescribing.

Principle 1:
We believe widespread adoption of e-prescribing can provide many benefits, including:

- Improved medication safety
- Enhanced practice efficiency
- Cost savings
- More effective medication management
- Increased patient adherence
- Improved integrity of the prescribing process

Principle 2:
All health care stakeholders should collaborate to encourage widespread adoption and optimal use of standards-based e-prescribing through:

- Appropriately aligned incentives to support effective use of the technology in diverse practice settings
- Collaborative development and delivery of innovative programs, education resources, training, and support
- Efficiencies in workflow for the physician and pharmacist in diverse practice settings;
- Connectivity and tools to facilitate medication reconciliation, formulary and medication history information, and transmission

Principle 3:
E-prescribing system design and/or the implementation of e-prescribing should:

- Enhance the patient-clinician relationship by providing more comprehensive clinical information at the point of care
- Preserve the patient's choice of pharmacy
- Facilitate the clinician's informed choice of medication
- Be part of an integrated plan toward full implementation of an electronic health record

Principle 4:
Both electronic health records (EHRs) and stand-alone e-prescribing may be utilized to realize the functionality and benefits of e-prescribing. Overall quality of care can be enhanced by implementation of e-prescribing that is integrated within an EHR.

Principle 5:
Consumer organizations, providers, pharmacists, payers, and educators should help patients understand and experience the benefits of e-prescribing. Informed patients will play an important role in the encouragement for providers and pharmacists to use e-prescribing.

ACKNOWLEDGEMENTS

A Clinician's Guide to Electronic Prescribing is a collaborative effort of the eHealth Initiative, the Center for Improving Medication Management, the American Medical Association, the American College of Physicians, the American Academy of Family Practice, and the Medical Group Management Association.

A multi-stakeholder Steering Group also provided strategic guidance and participated in the creation of the Guide, offering their time, expertise and insights to the development of the report, and we are extremely grateful for their invaluable input and extraordinary contributions. The following individuals participated on the Steering Group:

Donald C. Huonker, RPh
Senior Vice President
Healthcare Innovation
Walgreens

James Morrow, MD
Vice President and Chief Information
Officer
North Fulton Family Medicine

Ken Majkowski, PharmD
Vice President
Clinical Affairs and Product Strategy
SureScripts-RxHub, LLC

James Walker, MD, FACP
Chief Medical Information Officer
Geisinger Health System

Janet M. Marchibroda
Chief Executive Officer
eHealth Initiative and eHealth Initiative
Foundation

About the eHealth Initiative
The eHealth Initiative and its Foundation are independent, nonprofit affiliated organizations whose missions are the same: to drive improvements in the quality, safety, and efficiency of health care through information and information technology.

eHI engages multiple stakeholders, including clinicians, consumer and patient groups, employers, health plans, health care IT suppliers, hospitals and other providers, laboratories, pharmaceutical and medical device manufacturers, pharmacies, public health, and public sector agencies, as well as its growing coalition of more than 250 state, regional, and community-based collaboratives, to develop and drive the adoption of common principles, policies, and best practices for improving the quality, safety, and effectiveness of America's health care through information and information technology. For more information on the eHealth Initiative, go to http://www.ehealthinitiative.org

About the Center for Improving Medication Management
The Center for Improving Medication Management serves as an industry resource by gathering and disseminating best and worst practices related to technology deployment for electronic medication management and for leveraging that technology and connectivity to test innovative approaches to improve patient adherence with prescribed medications. The Center was founded by American Academy of Family Physicians (AAFP), Blue Cross Blue Shield Association, Humana Inc., Intel Corporation, the Medical Group Management Association (MGMA), and SureScripts-RxHub. More information about The Center is available at http://www.theCIMM.org.

About the American Medical Association
The American Medical Association (AMA) helps doctors help patients by uniting physicians nationwide to work on the most important professional, public health and advocacy issues in medicine. Working together, the AMA's quarter of a million physician and medical student members are playing an active role in shaping the future of medicine. For more information on the AMA, please visit www.ama-assn.org.

About the American Academy of Family Physicians
The American Academy of Family Physicians is one of the largest national medical organizations, representing more than 94,000 family physicians, family medicine residents, and medical students nationwide. Founded in 1947, AAFP's mission has been to preserve and promote the science and art of family medicine and to ensure high-quality, cost-effective health care for patients of all ages.

About the American College of Physicians
The American College of Physicians (ACP) is a national organization of internists — physicians who specialize in the prevention, detection and treatment of illnesses in adults. ACP is the largest medical-specialty organization and second-largest physician group in the United States. Its membership of 126,000 includes internists, internal medicine subspecialists, and medical students, residents, and fellows. ACP's mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine.

About the Medical Group Management Association
MGMA is the nation's principal voice for the medical group practice profession, with 21,500 members who lead and manage more than 13,500 organizations in which almost 270,000 practice. MGMA's mission is to continually improve the performance of medical group practice professionals and the organizations they represent.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: December 2, 2008

To: Enforcement Committee

Subject: Fingerprinting Initiative of the Department of Consumer Affairs for Health-Related Boards

For a number of years the board has fingerprinted all applicants to secure criminal background information before issuing a license. On November 4, 2008, Director Carrie Lopez issued a memo to all Executive Officers and Bureau Chiefs under the department's purview setting out expectations for enforcement and public disclosures.

One of the specific requirements detailed by the director is that all health boards within the Department implement a plan for securing fingerprints from all licensees regardless of when they were first licensed.

When researching the possible impact to board operations to implement such a change, staff learned that the board was fingerprinting pharmacist applicants as early as September 1949, and we estimate that approximately 150 currently licensed before this date were not fingerprint cleared with the Department of Justice. It is unclear when the board began requiring fingerprints for business owners.

In 2001, the Department of Justice began transitioning to electronic submission of fingerprints, LiveScan. Fingerprint background information collected since that time is stored electronically. However, pre-existing fingerprint information was not converted into this electronic format. Given that full conversion of previous records is unlikely to occur, the committee should consider a recommendation to require licensees to resubmit fingerprints as a condition of renewal.

Also, while the Director's memo does not direct us to do so, the board also instituted federal background checks on most of our individual and business applicants beginning in 2000. To ensure consistency, we will begin requiring both state and federal background checks for all applicants.

Following is a copy of the memo from the Director as well as recently adopted emergency regulations pursued by the Board of Registered Nursing authorizing the collection of fingerprints as part of the renewal process for registered nurses.

It is our understanding that the department will be pursuing legislation next year to affirm the statutory authority to support the collection of fingerprints are part of the renewal

process. This draft language has not been released from the department, but will be provided at a future meeting.

In the interim, we are requesting the establishment of a Criminal Conviction Unit to investigate subsequent arrest and conviction information received from the Department of Justice on board licensees. This unit will be comprised of six staff dedicated to the retrieval, review and investigation of subsequent arrests and convictions – "rap sheets." In addition, the unit will be responsible for the immediate review of a rap sheet to determine the category of conviction, whether it is substantially related to the duties, qualifications and functions of a licensee, the seriousness of the offense and the imminent threat to the health and safety of the public.

The board receives approximately 3000 arrest notifications a year. The creation of this unit will ensure the timely review and investigation of such notifications and allow the board to pursue administrative action as necessary in the interest of public protection. The projected costs for this unit will be provided at the committee meeting.

STATE OF CALIFORNIA

dca
DEPARTMENT OF CONSUMER AFFAIRS

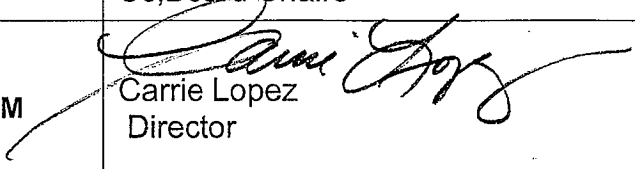STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR

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2008 NOV -7 PM 3: 58

MEMORANDUM

DATE	November 4, 2008
TO	Executive Officers and Bureau Chief Cc;Board Chairs
FROM	Carrie Lopez Director
SUBJECT	**Enforcement and Public Disclosures**

Over the last several weeks, my office has been in contact with you concerning a number of enforcement and public disclosure issues impacting DCA's health-related regulatory entities.

This memo memorializes those communications and sets forth my expectations as Director of the Department of Consumer Affairs.

Fingerprinting of Existing Licensees

As Director, I have determined that fingerprinting is an important background and monitoring tool that allows the Department and its regulatory entities to be made aware of criminal activity committed by any of its licensees. There is clear public benefit to the implementation of such a program.

I am hereby directing that all health boards under the Department implement a plan for securing fingerprints from all its licensees irrespective of when they were first licensed. All plans shall ensure that fingerprints will be obtained in a time equal to, or shorter than, the renewal period for each licensing category.

As you know, by obtaining licensee fingerprints, our programs have the ability to obtain subsequent arrest information from the Department of Justice and are better positioned to take enforcement actions against those who pose a significant risk to the public.

It is the Department's position that this change can be accomplished through the regulatory process. The Board of Registered Nursing recently adopted emergency regulations to implement such a program. The regulations are subject to Office of Administrative Law approval, and we expect them to be approved in November.

We will keep you apprised of the status of these regulations as they may serve as a model for your regulatory entity.

The Department will also be seeking statutory affirmation of this authority in an effort to remove any ambiguity that may exist and will support administrative or budgetary requests necessary to accommodate your collection of fingerprints from your licensee population.

Licensing Renewal Forms
In order to provide an additional level of assurance, each health-related board/bureau shall include on its renewal form a requirement that each applicant disclose any criminal convictions or disciplinary action taken by another government agency within or outside the state.

While fingerprints should allow each program to receive information from DOJ concerning any arrests or convictions, a non responsive or untruthful answer can provide an additional basis to take appropriate disciplinary action.

This change is ministerial and regulations are not necessary to implement any needed form modifications

The Department's Office of Information Services will facilitate the form modifications necessary and the change is expected to be effected in approximately one week's time

Publication of Accusations on Board Websites
While many entities currently post accusations on their website, many only include summaries or require consumers to contact them directly to obtain copies. As Director, I have determined that greater transparency and consistency are in the interest of consumer protection.

Effective immediately, I am directing all health-related entities to publish all pending accusations on their websites in their entirety. Furthermore, from this point forward, any new accusation shall also be placed in its entirety on the board or bureau's website. To the extent that any board requires equipment or assistance in making these documents available to the public, the Office of Information Services is available to provide assistance.

Interim Suspension Orders
The Department also wishes to emphasize the availability and desirability of pursuing interim suspension orders when the public's health and safety will be compromised by the continued practice of a licensee.

The Office of Legal Affairs will be distributing a copy of this policy to each of you within the next seven days and will provide examples of offenses that should be considered threatening to the health and safety of the public.

The Office stands ready to assist each of you in facilitating and/or coordinating any request for a suspension order with the Attorney General's Office.

Review of Pending Investigations/Accusations
I am hereby directing that each board review each of its active investigations and/or pending accusations to determine if more aggressive action is needed to ensure the

public's protection. Such action could involve prioritizing investigations with the Division of Investigations; securing timely administrative hearing dates with the Office of Administrative Hearings; or immediate action by the Attorney General's Office to secure an interim licensing suspension. Both the Executive Office and the Office of Legal Affairs stands ready to assist if needed.

Thank you in advance for your support.

BOARD OF REGISTERED NURSING

ORDER OF ADOPTION

(1) Amend section 1419 of Division 20 of Title 16 of the California Code of Regulations to read as follows:

1419. Renewal of License.

(a) A renewal application shall be on the form provided by the board, accompanied by the fee specified in Section 1417(a)(3) and required information and filed with the board at its office in Sacramento.

(b) For a license that expires on or after March 1, 2009, as a condition of renewal, an applicant for renewal not previously fingerprinted by the board, or for whom a record of the submission of fingerprints no longer exists, is required to furnish to Department of Justice, as directed by the board, a full set of fingerprints for the purpose of conducting a criminal history record check and to undergo a state and federal level criminal offender record information search conducted through the Department of Justice. Failure to submit a full set of fingerprints to the Department of Justice on or before the date required for renewal of a license is grounds for discipline by the board. It shall be certified on the renewal form whether the fingerprints have been submitted. This requirement is waived if the licensee is renewed in an inactive status, or is actively serving in the military outside the country.

(c) As a condition of renewal, an applicant for renewal shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490, of any violation of the law in this or any other state, the United States, or other country, omitting traffic infractions under $300 not involving alcohol, dangerous drugs, or controlled substances.

(d) Failure to provide all of the information required by this section renders any application for renewal incomplete and not eligible for renewal.

NOTE: Authority cited: Sections 2708.1, 2715 and 2761(f), Business and Professions Code. Reference: Sections 2715, 2761(f) and 2811, Business and Professions Code; and Section 11105(b)(10), Penal Code.

(2) Amend section 1419.1 of Division 20 of Title 16 of the California Code of Regulations to read as follows:

1419.1. Inactive License.

A license may be maintained in an inactive status by paying the renewal fee as it becomes due. The licensee shall not practice nursing during the time the license is inactive.

To activate an inactive license, the licensee must submit a written request and evidence of 30 hours of approved continuing education taken during the two-year period immediately

preceding the request for activation. A licensee activating a license pursuant to this section shall furnish a full set of fingerprints as required by and set out in section 1419(b) as a condition of activation.

NOTE: Authority cited: Sections 2708.1, 2715 and 2761(f), Business and Professions Code. Reference: Sections 2734 and 2761(f), Business and Professions Code; and Section 11105(b)(10), Penal Code.

(3) Amend section 1419.3 of Division 20 of Title 16 of the California Code of Regulations to read as follows:

1419.3. Reinstatement of Expired License.

In the event a licensee does not renew his/her license as provided in Section 2811 of the code, the license expires. A licensee renewing pursuant to this section shall furnish a full set of fingerprints as required by and set out in section 1419(b) as a condition of renewal.

(a) A licensee may renew a license that has not been expired for more than eight years by paying the renewal and penalty fees as specified in Section 1417 and providing evidence of 30 hours of continuing education taken within the prior two-year period.

(b) A licensee may renew a license that has been expired for more than eight years by paying the renewal and penalty fees specified in Section 1417 and providing evidence that he or she holds a current valid active and clear registered nurse license in another state, a United States territory, or Canada, or by passing the Board's current examination for licensure.

NOTE: Authority cited: Sections 2708.1, 2715, 2761(f), and 2811.5, Business and Professions Code. Reference: Sections 2761(f), 2811 and 2811.5, Business and Professions Code; and Section 11105(b)(10), Penal Code.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: December 2, 2008

To: Enforcement Committee

Subject: Cite and Fine Program

During the Enforcement Committee Meeting, Supervising Inspector Bob Ratcliff will provide an overview of the citations and fines issued by the board during fiscal years 2006-07 and 2007-08. This presentation was requested by President Schell and CPhA, following the board's specific presentation on citations and fines for prescription errors that was presented at the July 2008 Board Meeting.

In anticipation of this presentation, Fred Mayer has submitted a list of items and questions he requests answers to (attached).   Among his concerns are that workplace issues are responsible for the prescription errors, yet fines in the $50,000 - $100,000 range are not being issued to corporate officers.

His specific concerns include:
1. Why are pharmacy technicians not cited often?
2. Why is chain pharmacy or corporate management not cited?
3. Why is the cause of the error not listed in the citation?

PPSI <ppsi@aol.com>
12/01/2008 11:39 AM

To virginia_herold@dca.ca.gov

cc

bcc

Subject Enforcement Committee Meeting, Dec. 9, 9:30 a.m. - 1 p.m.,
Item #5 (1) "Citation & Fine Program Overview 07-08"

>

Virginia Herold, CEO   Fax   916 574-8618
 California State Board of Pharmacy   Phone 916 574-7911
1625 North Market Boulevard #N219
Sacramento, CA 95834

RE: CALIFORNIA BOARD OF PHARMACY CITATION AND FINE PROGRAM
OVERVIEW 2007-2008
      ITEM #5 MEETING AGENDA, ENFORCEMENT COMMITTEE, DECEMBER 9, 2008;
9:30 A.M. - 1 P.M.

Dear Giny:

PPSI, a 501 C (3) nonprofit, public health, consumer, pharmacy education organization would
like to comment on next week's December 9th Enforcement Committee Meeting on Item No. 5
"Citation and Fine Program Overview, 2007-2008", as follows (as I am unable to attend):

  1. The California BOP sent PPSI under the Public Records Act Request, Prescription Errors,
June 31, 2007-January 1, 2008 and also under Public Records, January 1, 2007-June 30, 2007 for
review.

  2. In reviewing these citations and fines, PPSI noticed that the fines were almost in all
incidences or a majority of incidences fines for violation against pharmacy staff members and for
pharmacists-in-charge (PIC).

  3. In some instances we were able to find where licensed pharmacy technicians were fined, but
very rarely.

  4. PPSI was unable for the January 1, 2007-January 1, 2008 year to find where the BOP fined
pharmacy management, chain pharmacy CEOs or corporate management in charge of Walgreens,
Rite Aid, Longs, SaveOn, Costco, CVS, etc.

  5. PPSI was also unable to find in the citation and fine correspondence and material issued by
the Board the cause of the prescription drug errors, such as understaffing, stressed out
pharmacists' issues, confusion in the pharmacy, lack of adequate supervision, & basically time to
review patient profiles and records along with failure to consult and what caused these incidences
to increase.

6. In once cite and fine the pharmacist was fined $10,000; the tech was fined, the pharmacist in charge was fined, but I did not see one fine against the hospital for having tech-check-tech. IS THERE PERHAPS SOMETHING IN THE CALIFONIA BOP STATUTE THAT SAYS THAT MANAGEMENT WHO CONTROLS STAFFING AT HOSPITALS, CHAIN, INDEPENDENT, HMO PHARMCIES CANNOT BE FINED?

7. In many cases, as a pharmacist for over 55 years licensed in California, issues such as erroneous or uncertain prescriptions, variation from prescription, dispensing Rx's which contained significant errors or omissions, quality assurance findings, obligation to consult, etc. are due to understaffing and improper working conditions including long hours, low blood sugars, proper lunch hours, etc.

8. Below are letters from CPhA's Academy of Employee Pharmacists articulating some of the above issues - especially the workplace issue resulting in stress and increase of errors.

I would appreciate your reading the information above and below and bringing these items up before the Board under Item #5 and what can be done to prevent errors through the Enforcement Committee when the primary cause of errors might be due to insufficient staffing, failure to counsel, and looking at the patient profile due to stressed out working conditions.

PPSI has met four times with the Board on pharmacists filling over 200 Rx's in an eight hour shift with inadequate help and understaffing conditions. We believe that by increasing cites and fines in the amounts of $50,000 to $100,000 at the corporate level, would be in the best interest of preventing prescription drug errors.

Please advise why these fines are not being levied against the corporations who control the pharmacy setting including hiring and firing and workplace conditions along with standards of practice.
Sincerely,

Fred S. Mayer, RPh, MPH
President, PPSI
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **December 2, 2008**

To: **Enforcement Committee**

Subject: **DEA Policy on Correcting Schedule II Prescriptions**

In October 2008, the board received clarification from the Drug Enforcement Administration on the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921) as it relates to the changes that can be made by a pharmacist.

As highlighted by the DEA, the preamble to the final rule is in conflict with information posted on the DEA's website regarding changes a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

In light of this confusion, the DEA is instructing pharmacists to adhere to state regulations or policy until this matter is resolved through a future rulemaking.

California law does not specifically indicate what changes a pharmacist can make to a Schedule II prescription.   Rather our law provides that both the date and signature of the physician must be in the prescriber's handwriting. California Code of Regulations Section 1761 (a) allows for a pharmacist to contact a prescriber for oral clarification on a prescription that is ambiguous, erroneous, irregular, uncertain or contains an omission, unless that omission is the prescriber's signature or date. Board staff will be available to respond to committee questions.

Following is a copy of the DEA notification.

OCT 1 5 2008

Dear Colleague:

On November 19, 2007, the Drug Enforcement Administration (DEA) published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the Rule's preamble are in opposition to policy posted on the DEA Diversion website regarding changes a pharmacist may make to a schedule II prescription after oral consultation with the prescriber. In a Question and Answer section, the website instructed that a "pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner."

DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.

Questions regarding this correspondence may be directed to the Liaison and Policy Section, Office of Diversion Control, DEA at (202) 307-7297.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator/
Deputy Chief of Operations
Office of Diversion Control

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **December 2, 2008**

To: **Enforcement Committee**

**Subject: Theft of Dangerous Drugs from the Pharmaceutical Supply Chain**

California Pharmacy Law requires that all deliveries of dangerous drugs and devices may only be received by and signed for by a pharmacist or designated representative. Further, the law specifies that delivery of such products to a hospital's central receiving area must be subsequently delivered to the hospital pharmacy within one working day, and the pharmacist on duty must immediately inventory the products. (Business and Professions Code Section 4059.5(a) and (c))

Board staff received correspondence from Kaiser Permanente requesting the board's assistance in communicating the delivery requirements for dangerous drugs and devices to pharmacies. According to information received from Kaiser, despite numerous attempts to address this issue with common carriers like Fed Ex and UPS, deliveries are still made to unauthorized locations.

The board does not regulate common carriers, nor is there any requirement in pharmacy law requiring such licensure to handle dangerous drugs and devices. However, board licensees are responsible for ensuring the appropriate delivery, receipt and handling of such products.

In July 2008, the board included an article in *The Script*, which highlighted the problem of drug diversion from common carriers and stated that the board, as well as the DEA, hold licensees/registrants accountable for failing to take actions to prevent, discover, and report in-transit thefts as required by law. This article highlighted that as a result of these thefts, dangerous drugs are sold on the street, on the Internet, or introduced into the medication supply chain by being sold to pharmacies and wholesalers.

Following is a copy of the article included in the July 2008 as well as the correspondence received from Kaiser.
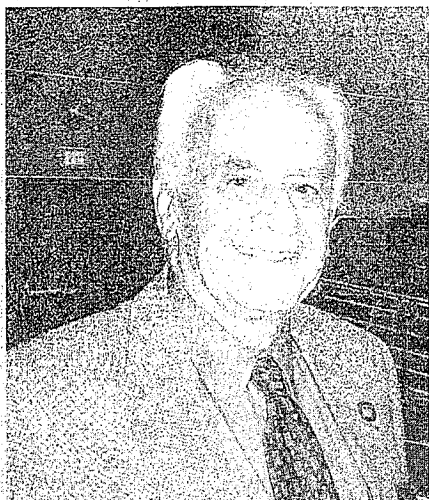
President's Message

By William Powers,
Public Member,
President, Board of Pharmacy

This is my last message as President of the Board of Pharmacy, and I am looking back with satisfaction at some of the issues the Board has addressed during my two-year tenure as president. Two of my priorities were to increase the Board's outreach programs aimed at senior citizens and to educate licensees in ways to reduce medication errors.

One of the Board's largest undertakings during my tenure has been to implement the e-Pedigree requirements for prescription drugs dispensed or shipped through California. The e-Pedigree system enables the tracking of prescription drugs all the way from the manufacturer to the pharmacy, reducing the threat of counterfeit or diverted drugs from entering the medication supply chain. It also will enable identification and prosecution of those who divert drugs. The Board continues to confer with all interested parties to make e-Pedigree happen at the earliest possible date. Implementation of these requirements is an enormous undertaking for the pharmaceutical supply chain.

The Board is working to implement SB 472 (Corbett, Chapter 470, Statutes of 2007), requiring the development of a standardized prescription container label for all California patients by 2011. Information gathering meetings are scheduled, and all interested parties, including the public, are invited to attend and provide input.

The Board has been working with other agencies, including the Integrated Waste Management Board, the Department of Toxic Substances Control, and the State Water Resources Control Board, to implement SB 966 (Simitian, Chapter 542, Statutes of 2007) regarding drug "take back" programs for consumers. This law calls for the development of model programs for the collection and proper disposal of drug waste by December 2008.

Another Board project has been the development and adoption of the Board's Disaster Response Policy Statement. Hurricane Katrina and the devastating wildfires of Southern California accentuated the need for an overall plan of operation to protect the health and safety of the public during declared emergencies. The policy statement advises Board licensees that pharmacy law can be waived during federal or local emergencies to provide care to patients. The statement also encourages health care providers to volunteer their time and expertise to assist and care for those whose lives are totally disrupted during disastrous events.

It has been my great pleasure to work on such ambitious and wide-reaching programs, and to work with such a visionary group of board members and terrific staff. They are all dedicated to promoting the health and safety of all Californians.

Licensees can be held accountable for drug delivery thefts

Medication drugs stolen from drug transportation companies are a serious problem nationwide. These stolen drugs are sold on the street, on the Internet, or introduced into the medication supply chain by being sold at heavily discounted prices to pharmacies or wholesalers. When the stolen drugs enter the medication supply chain, unsuspecting consumers face potential health and safety risks from legitimate products, which may have been mishandled by the criminal enterprises. Improper storage or adulteration of the stolen drugs can pose a significant health hazard to consumers when reintroduced into the retail market.

Apart from the more sensational instances where more than 16 million doses of hydrocodone combination products were

stolen from a tractor-trailer parked at a truck stop or a courier van containing 2,000 tablets of hydrocodone and approximately 200 tablets of oxycodone was stolen while the driver was inside delivering the freight, there are smaller but significant thefts that occur in-transit. Licensees must be aware that the Board and DEA hold registrants accountable for failing to take actions to prevent, discover, and report in-transit thefts as required by law.

For example, a pharmacist-in-charge was cited and fined by the Board because she signed for a delivery and did not open the container until later. Upon opening the container, the PIC discovered that the box contained objects other than the controlled substances listed in the shipment. The PIC was cited

Licensees

Continued from Page 2

for violation of Business & Professions Code section 4059.5 for signing for the shipment and failing to immediately examine the shipment contents. Wholesalers and the receiving pharmacies have also been cited and fined for allowing non-pharmacists (pharmacy technicians) to accept and sign for drug deliveries.

Wholesalers and pharmacies are equally responsible for the careful review of all pharmaceutical shipments and must report any short shipments to the DEA and the police, and the loss of any controlled substance must be reported to the Board of Pharmacy within 30 days of discovery (Title 16, California Code of Regulations section 1715.6).

Preventing and discovering in-transit thefts include strict monitoring and review of drug shipments at every point from the manufacturer to the pharmacy. The manufacturer is responsible for checking the shipment amounts before the shipment leaves the facility, and the receiving wholesaler must then review the shipment for correct amounts before delivering or passing the shipment on to a contracted carrier. The wholesaler carrier is then responsible for the shipment until the receiving pharmacist signs for it. Consequently, the receiving pharmacist must immediately open and inspect the shipment to ensure that the boxes contain the correct products and amounts, because once the pharmacist signs off on the shipment, the responsibility for the shipment's contents becomes his or hers.

Other ways of preventing in-transit theft are for manufacturers to refrain from including the drug's name on the outside of the shipping container and for wholesalers to investigate the backgrounds of any carriers with whom they contract. A licensed wholesaler may be operating within the law, but many wholesalers use ground couriers who might then subcontract other couriers of varying sizes and standards of professionalism.

At its November 2007 meeting, the National Association of Boards of Pharmacy created the NABP Task Force on Prescription Drug Diversion from Common Carriers. The task force was created as a result of a resolution passed at their annual meeting in May 2007 that noted:

(1) The diversion of prescription medication from common carriers presents a threat to the public health; and
(2) Regulations regarding the distribution and delivery of prescription drugs vary by state and often do not include accountability provisions for common carriers that distribute and deliver prescription drugs.

The charge of the task force is to study issues surrounding the diversion of prescription drugs from common carriers or their agents during interstate and intrastate distribution and delivery to wholesalers, pharmacies, patients, and patients' agents and to recommend possible solutions.

Meanwhile, everyone involved in the delivery of controlled substances, from the manufacturer to the pharmacy, must be aware of and compliant with the laws that are in place to prevent, discover, and report in-transit theft. The following sections relate to these laws

Business & Professions Code section 4059.5(a) and (c) requires that:

- Deliveries of dangerous drugs or dangerous devices to a pharmacy may only be received and signed for by a pharmacist, and if delivered to a wholesale facility, may only be received and signed for by a designated representative.
- Deliveries of dangerous drugs or dangerous devices to a hospital's central receiving area must be subsequently delivered to the hospital pharmacy within one working day, and the pharmacist on duty must immediately inventory the dangerous drugs or devices.

The prompt inventorying of drug shipments to hospitals brings up the issue of drug deliveries to pharmacies that are part of a hospital but are located away from the hospital building and as such, are licensed as community pharmacies. Apparently, carriers often leave shipments for these facilities in the hospital receiving area instead of delivering them directly to the offsite pharmacy. Provisions should be made by the hospitals to assure that such deliveries are properly directed.

Title 16, California Code of Regulations section 1715.6 requires the pharmacy owner to report to the Board of Pharmacy within 30 days of the discovery of a drug loss.

Health & Safety Code section 11103 requires that any theft, loss, or shipping discrepancy must be reported to the Department of Justice within three days after the discovery.

Health & Safety Code section 11209 prohibits the delivery or acceptance of Schedule II, III, and IV controlled substances unless signed for by a pharmacist or authorized receiving personnel, and any discrepancy between the receipt and actual contents must be reported to the delivering wholesaler or manufacturer by the next business day after delivery. The delivery receipt and record of discrepancy must be maintained by the wholesaler or manufacturer for three years. *Violation of this section is a misdemeanor.*

Title 21 of the Code of Federal Regulations section 1301.74(e) holds suppliers responsible for "reporting [to DEA] in-transit losses of controlled substances by the common or contract carrier selected upon discovery of such theft or loss.... Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them."

Preventing, discovering, and reporting in-transit drug thefts are everyone's responsibility.

January 31, 2008

State Board of Pharmacy
1625 N. Market Street N219
Sacramento, CA 95834

Dear Board Members:

Kaiser Permanente is asking for your assistance in educating and gaining compliance from the top common carriers UPS, FedEx, and DHL etc regarding Business and Professions Code 4059.5 That law requires dangerous drugs (as defined) to be delivered by common carriers directly to each licensed pharmacy, except for hospital pharmacies.

The common couriers are generally compliant with this code for hospital pharmacies which allows delivery by the common carrier to the hospital loading, receiving dock. They are not generally compliant regarding pharmacies that are located outside a hospital i.e. pharmacies operating as community pharmacies with a "PHY" license prefix due to the carriers refusing to deliver directly to the pharmacy. We have on many occasions contacted these companies at local and national levels and have been unsuccessful at obtaining substantial compliance.

We would like the Board to formally notify these companies to educate and warn them on their lack of legal compliance with California law. Their lack of compliance does not only affect Kaiser Permanente but many other pharmacies which receive dangerous drugs from these common carriers. I have listed the addresses of the top three common carriers corporate offices. If you should need any further information please feel free to contact me.

Thank you,

Steve W. Gray

FedEx Corporate Contributions
3610 Hacks Cross Road
Building A, First Floor
Memphis, TN 38125
Phone: 901-369-3600

UPS Corporate Headquarters
55 Glenlake Parkway, NE
Atlanta, GA 20214
Phone: 404-828-6000

DHL Express
1200 South Pine Island Road Suite 600
Plantation, FL 33324

Anne
Sodergren/Pharmacy/DCANo
tes

12/03/2008 01:20 PM

To

cc

bcc

Subject   Fw: UPS Delivery Issues

Steve.W.Gray@kp.org

Steve.W.Gray@kp.org

11/06/2008 12:01 PM

To   Virginia_Herold@dca.ca.gov

cc

Subject   Fw: UPS Delivery Issues

Several years ago, after receiving a "Correction Notice", we committed to the Board of Pharmacy to try our best to get the Rx Drug deliveries to be delivered DIRECTLY to the licensed pharmacies (as required by statute B&P 4059.5) in our medical facilities, vs. being "dropped off" at the "loading dock" and be handled by our non-pharmacy, materials Management (MM) personnel. It has been frustrating and not very successful. Several months ago, I believe at an Enforcement Committee meeting, I ask if the BoP would officially contact the main carriers, e.g. UPS and FedEx with some kind of "encouragement" to follow the law. I simply cannot remember what the BoP decided to do or if it already acted?

Do you need more from us? Is anything planned? Is this still an important issue, relative to other issues "we" face? Frankly, when I check with other organizations, they virtually all say they have the same problem but they are making no effort to change the delivery practices. We have repeatedly contacted the carriers' National leadership and we get statements that things will change. I believe that the UPS change described below is an effort but as you can see we are still having trouble. I believe that if it is important to the BoP, we need its help.

Steven W Gray, PharmD, JD
Kaiser Permanente, California Pharmacy Regulatory Compliance and Professional Affairs Leader

----- Forwarded by Steve W Gray/CA/KAIPERM on 11/06/2008 11:48 AM -----